COMMISSION OF THE EUROPEAN COMMUNITIES

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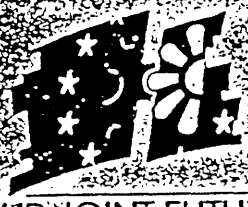

OUR JOINT FUTURE

DG XI FOR THE QUALITY OF LIFE

HANDBOOK

FOR THE IMPLEMENTATION OF DIRECTIVE 90/220/EEC ON THE DELIBERATE RELEASE OF GENETICALLY MODIFIED ORGANISMS TO THE ENVIRONMENT

MAY 1992

DIRECTORATE GENERAL XI
ENVIRONMENT, NUCLEAR SAFETY
AND CIVIL PROTECTION

CONTENTS

FOREWORD

Since the adoption of Directive 90/220/EEC in April 1990, experts on biotechnology from the twelve Member States of the European Community have met regularly, at first as the Group of National Experts on Biotechnology and then as the Committee of Competent Authorities, to discuss details of implementing the Directive. The objective has been to reach agreement by consensus on a uniform and clear interpretation of the text, and also to prepare a number of documents referred to in the Directive. This handbook brings together the results so far achieved jointly by all the Member State Authorities, who have discussed and agreed the texts as formulated. Some of the texts have formal legal status and others not, but the principles are incorporated either in national legislation or in the administrative practice in implementing the Directive in the Member States.

The Competent Authorities and representatives from the Commission will continue to meet regularly to discuss aspects of implementation not covered by the present handbook and to revise the existing notes in light of the experience gained by the implementation of the Directive. The handbook will be revised and supplemented accordingly.

The handbook is a compilation of existing documents, providing guidance for the implementation of the Directive. It is intended to assist the Competent Authorities in their work, to guide those intending to release GMOs, and to generally inform interested groups and the public at large. It should be noted that the content of this handbook is for information only. None of the texts modify in any way the text of the Directive nor do they prejudice the legal interpretation of the Directive which can only be provided by the Court of Justice.

COUNCIL DIRECTIVE

of 23 April 1990

on the deliberate release into the environment of genetically modified organisms

(90/220/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission (1),

In cooperation with the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas, under the Treaty, action by the Community relating to the environment should be based on the principle that preventive action should be taken;

Whereas living organisms, whether released into the environment in large or small amounts for experimental purposes or as commercial products, may reproduce in the environment and cross national frontiers thereby affecting other Member States; whereas the effects of such releases on the environment may be irreversible;

Whereas the protection of human health and the environment requires that due attention be given to controlling risks from the deliberate release of genetically modified organisms (GMOs) into the environment;

Whereas disparity between the rules which are in effect or in preparation in the Member States concerning the deliberate release into the environment of GMOs may create unequal conditions of competition or barriers to trade in products containing such organisms, thus affecting the functioning of the common market; whereas it is therefore necessary to approximate the laws of the Member States in this respect;

Whereas measures for the approximation of the provisions of the Member States which have as their object the establishment and functioning of the internal market should, inasmuch as they concern health, safety, environmental and consumer protection, be based on a high level of protection throughout the Community;

Whereas it is necessary to ensure the safe development of industrial products utilizing GMOs;

Whereas this Directive should not apply to organisms obtained through certain techniques of genetic modification which have conventionally been used in a number of applications and have a long safety record;

Whereas it is necessary to establish harmonized procedures and criteria for the case-by-case evaluation of the potential risks arising from the deliberate release of GMOs into the environment;

Whereas a case-by-case environmental risk assessment should always be carried out prior to a release;

Whereas the deliberate release of GMOs at the research stage is in most cases a necessary step in the development of new products derived from, or containing, GMOs;

Whereas the introduction of GMOs into the environment should be carried out according to the 'step by step' principle; whereas this means that the containment of GMOs is reduced and the scale of release increased gradually, step by step, but only if evaluation of the earlier steps in terms of protection of human health and the environment indicates that the next step can be taken;

Whereas no product containing, or consisting of, GMOs and intended for deliberate release shall be considered for placing on the market without it first having been subjected to satisfactory field testing at the research and development stage in ecosystems which could be affected by its use;

Whereas it is necessary to establish a Community authorization procedure for the placing on the market of products containing, or consisting of, GMOs where the intended use of the product involves the deliberate release of the organism(s) into the environment;

Whereas any person, before undertaking a deliberate release into the environment of a GMO, or the placing on the market of a product containing, or consisting of, GMOs, where the intended use of that product involves its deliberate release into the environment, shall submit a notification to the national competent authority;

Whereas that notification should contain a technical dossier of information including a full environmental risk assessment, appropriate safety and emergency response, and, in the case of products, precise instructions and conditions for use, and proposed labelling and packaging;

(1) OJ No C 198, 28. 7. 1988, p. 19 and OJ No C 246, 27. 9. 1989, p. 5.
(2) OJ No C 158, 26. 6. 1989, p. 225 and OJ No C 96, 17. 4. 1990.
(3) OJ No C 23, 30. 1. 1989, p. 45.

Whereas, after notification, no deliberate release of GMOs should be carried out unless the consent of the competent authority has been obtained;

Whereas the competent authority should give its consent only after it has been satisfied that the release will be safe for human health and the environment;

Whereas it may be considered appropriate in certain cases to consult the public on the deliberate release of GMOs into the environment;

Whereas it is appropriate for the Commission, in consultation with the Member States, to establish a procedure for the exchange of information on deliberate releases of GMOs notified under this Directive;

Whereas it is important to follow closely the development and use of GMOs; whereas a list should be published of all the products authorized under this Directive;

Whereas, when a product containing a GMO or a combination of GMOs is placed on the market, and where such a product has been properly authorized under this Directive, a Member State may not on grounds relating to matters covered by this Directive, prohibit, restrict or impede the deliberate release of the organism in that product on its territory where the conditions set out in the consent are respected; whereas a safeguard procedure should be provided in case of risk to human health or the environment;

Whereas the provisions of this Directive relating to placing on the market of products should not apply to products containing, or consisting of, GMOs covered by other Community legislation which provides for a specific environmental risk assessment similar to that laid down in this Directive;

Whereas a Committee should be set up to assist the Commission on matters relating to the implementation of this Directive and to its adaptation to technical progress,

HAS ADOPTED THIS DIRECTIVE:

PART A

General provisions

Article 1

1. The objective of this Directive is to approximate the laws, regulations and administrative provisions of the Member States and to protect human health and the environment:

— when carrying out the deliberate release of genetically modified organisms into the environment,

— when placing on the market products containing, or consisting of, genetically modified organisms intended for subsequent deliberate release into the environment.

2. This Directive shall not apply to the carriage of genetically modified organisms by rail, road, inland waterway, sea or air.

Article 2

For the purposes of this Directive:

(1) 'organism' is any biological entity capable of replication or of transferring genetic material;

(2) 'genetically modified organism (GMO)' means an organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

Within the terms of this definition:

(i) genetic modification occurs at least through the use of the techniques listed in Annex I A Part 1;

(ii) the techniques listed in Annex I A Part 2 are not considered to result in genetic modification;

(3) 'deliberate release' means any intentional introduction into the environment of a GMO or a combination of GMOs without provisions for containment such as physical barriers or a combination of physical barriers together with chemical and/or biological barriers used to limit their contact with the general population and the environment;

(4) 'product' means a preparation consisting of, containing, a GMO or a combination of GMOs, which is placed on the market;

(5) 'placing on the market' means supplying or making available to third parties;

(6) 'notification' means the presentation of document containing the requisite information to the competent authority of a Member State. The person making the presentation shall be referred to as 'the notifier';

(7) 'use' means the deliberate release of a product which has been placed on the market. The persons carrying out this use will be referred to as 'users';

(8) 'environmental risk assessment' means the evaluation of the risk to human health and the environment (which includes plants and animals) connected with the release of GMOs or products containing GMOs.

Article 3

This Directive shall not apply to organisms obtained through the techniques of genetic modification listed in Annex

Article 4

1. Member States shall ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or placing on the market of GMOs.

2. Member States shall designate the competent authority or authorities responsible for carrying out the requirements of this Directive and its Annexes.

3. Member States shall ensure that the competent authority organizes inspections and other control measures as appropriate, to ensure compliance with this Directive.

PART B

Deliberate release of GMOs into the environment for research and development purposes or for any other purpose than for placing on the market

Article 5

Member States shall adopt the provisions necessary to ensure that:

(1) any person, before undertaking a deliberate release of a GMO or a combination of GMOs for the purpose of research and development, or for any other purpose than for placing on the market, must submit a notification to the competent authority referred to in Article 4 (2) of the Member State within whose territory the release is to take place;

(2) the notification shall include:

(a) a technical dossier supplying the information specified in Annex II necessary for evaluating the foreseeable risks, whether immediate or delayed, which the GMO or combination of GMOs may pose to human health or the environment, together with the methods used and the bibliographic reference to them and covering, in particular:

(i) general information including information on personnel and training,

(ii) information relating to the GMO(s),

(iii) information relating to the conditions of release and the receiving environment,

(iv) information on the interactions between the GMO(s) and the environment,

(v) information on monitoring, control, waste treatment and emergency response plans;

(b) a statement evaluating the impacts and risks posed by the GMO(s) to human health or the environment from the uses envisaged;

(3) the competent authority may accept that releases of a combination of GMOs on the same site or of the same GMO on different sites for the same purpose and within a limited period may be notified in a single notification;

(4) the notifier shall include in the notification information on data or results from releases of the same GMOs or the same combination of GMOs previously or currently notified and/or carried out by him either inside or outside the Community.

The notifier may also refer to data or results from notifications previously submitted by other notifiers, provided that the latter have given their agreement in writing;

(5) in the case of a subsequent release of the same GMO or combination of GMOs previously notified as part of the same research programme, the notifier shall be required to submit a new notification. In this case, the notifier may refer to data from previous notifications or results from previous releases;

(6) in the event of any modification of the deliberate release of GMOs or a combination of GMOs which could have consequences with regard to the risks for human health or the environment or if new information has become available on such risks, either while the notification is being examined by the competent authority or after that authority has given its written consent, the notifier shall immediately:

(a) revise the measures specified in the notification,

(b) inform the competent authority in advance of any modification or as soon as the new information is available,

(c) take the measures necessary to protect human health and the environment.

Article 6

1. On receipt and after acknowledgment of the notification the competent authority shall:

— examine it for compliance with this Directive,

— evaluate the risks posed by the release,

— record its conclusions in writing,

and, if necessary,

— carry out tests or inspections as may be necessary for control purposes.

2. The competent authority, having considered, where appropriate, any comments by other Member States made in accordance with Article 9, shall respond in writing to the notifier within 90 days of receipt of the notification by either:

(a) indicating that it is satisfied that the notification is in compliance with this Directive and that the release may proceed, or

(b) indicating that the release does not fulfil the conditions of this Directive and the notification is therefore rejected.

3. For the purpose of calculating the 90-day period referred to in paragraph 2, any periods of time during which the competent authority:

— is awaiting further information which it may have requested from the notifier,

or

— is carrying out a public inquiry or consultation in accordance with Article 7

shall not be taken into account.

4. The notifier may proceed with the release only when he has received the written consent of the competent authority, and in conformity with any conditions required in this consent.

5. If the competent authority considers that sufficient experience has been obtained of releases of certain GMOs, it may submit to the Commission a request for the application of simplified procedures for releases of such types of GMOs. The Commission shall, in accordance with the procedures laid down in Article 21, establish appropriate criteria and take a decision accordingly on each application. The criteria shall be based on safety to human health and the environment and on the evidence available on such safety.

6. If information becomes available subsequently to the competent authority which could have significant consequences for the risks posed by the release, the competent authority may require the notifier to modify the conditions of, suspend or terminate the deliberate release.

Article 7

Where a Member State considers it appropriate, it may provide that groups or the public shall be consulted on any aspect of the proposed deliberate release.

Article 8

After completion of a release, the notifier shall send to the competent authority the result of the release in respect of any risk to human health or the environment, with particular reference to any kind of product that the notifier intends to notify at a later stage.

Article 9

1. The Commission shall set up a system of exchange of the information contained in the notifications. The competent authorities shall send to the Commission, within 30 days of its receipt, a summary of each notification received. The format of this summary will be established by the Commission in accordance with the procedure laid down in Article 21.

2. The Commission shall immediately forward these summaries to the other Member States, which may, within 30 days, ask for further information or present observations through the Commission or directly.

3. The competent authorities shall inform the other Member States and the Commission of the final decisions taken in compliance with Article 6 (2).

PART C

Placing on the market of products containing GMOs

Article 10

1. Consent may only be given for the placing on the market of products containing, or consisting of, GMOs, provided that:

— written consent has been given to a notification under Part B or if a risk analysis has been carried out based on the elements outlined in that Part;

— the products comply with the relevant Community product legislation;

— the products comply with the requirements of this Part of this Directive, concerning the environmental risk assessment.

2. Articles 11 to 18 shall not apply to any products covered by Community legislation which provides for a specific environmental risk assessment similar to that laid down in this Directive.

3. Not later than 12 months after notification of this Directive, the Commission, in accordance with the procedure laid down in Article 21, shall establish a list of Community legislation covering the products referred to in paragraph 2. This list will be re-examined periodically and as necessary, revised in accordance with the said procedure.

Article 11

1. Before a GMO or a combination of GMOs are placed on the market as or in a product, the manufacturer or the importer to the Community shall submit a notification to the competent authority of the Member State where such product is to be placed on the market for the first time. The notification shall contain:

— the information required in Annex II, extended as necessary to take into account the diversity of sites of use of the product, including information on data and results obtained from research and developmental releases concerning the ecosystems which could be affected by the use of the product and an assessment of any risks for human health and the environment related to the GMOs or

combination of GMOs contained in the product, including information obtained from the research and development stage on the impact of the release on human health and the environment;

— the conditions for the placing on the market of the product, including specific conditions of use and handling and a proposal for labelling and packaging which should comprise at least the requirements laid down in Annex III.

If on the basis of the results of any release notified under Part B of this Directive, or on substantive, reasoned scientific grounds, a notifier considers that the placing on the market and use of a product do not pose a risk to human health and the environment, he may propose not to comply with one or more of the requirements of Annex III B.

2. The notifier shall include in this notification information on data or results from releases of the same GMOs or the same combination of GMOs previously or currently notified and/or carried out by the notifier either inside or outside the Community.

3. The notifier may also refer to data or results from notifications previously submitted by other notifiers, provided that the latter have given their agreement in writing.

4. Each new product which, containing or consisting of the same GMO or combination of GMOs, is intended for a different use, shall be notified separately.

5. The notifier may proceed with the release only when he has received the written consent of the competent authority in accordance with Article 13, and in conformity with any conditions, including reference to particular ecosystems/environments, required in that consent.

6. If new information has become available with regard to the risks of the product to human health or the environment, either before or after the written consent, the notifier shall immediately:

— revise the information and conditions specified in paragraph 1,

— inform the competent authority, and

— take the measures necessary to protect human health and the environment.

Article 12

1. On receipt and after acknowledgement of the notification referred to in Article 11, the competent authority shall examine it for compliance with this Directive, giving particular attention to the environmental risk assessment and the recommended precautions related to the safe use of the product.

2. At the latest 90 days after receipt of the notification, the competent authority shall either:

(a) forward the dossier to the Commission with a favourable opinion, or

(b) inform the notifier that the proposed release does not fulfil the conditions of this Directive and that it is therefore rejected.

3. In the case referred to in paragraph 2 (a), the dossier forwarded to the Commission shall include a summary of the notification together with a statement of the conditions under which the competent authority proposes to consent to the placing on the market of the product.

The format of this summary shall be established by the Commission in accordance with the procedure laid down in Article 21.

In particular where the competent authority has acceded to the request of the notifier, under the terms of the last subparagraph of Article 11 (1), not to comply with some of the requirements of Annex III B, it shall at the same time inform the Commission thereof.

4. If the competent authority receives additional information pursuant to Article 11 (6), it shall immediately inform the Commission and the other Member States.

5. For the purpose of calculating the 90-day period referred to in paragraph 2, any periods of time during which the competent authority is awaiting further information which it may have requested from the notifier shall not be taken into account.

Article 13

1. On receipt of the dossier referred to in Article 12 (3), the Commission shall immediately forward it to the competent authorities of all Member States together with any other information it has collected pursuant to this Directive and advise the competent authority responsible for forwarding the document of the distribution date.

2. The competent authority, in the absence of any indication to the contrary from another Member State within 60 days following the distribution date referred to in paragraph 1, shall give its consent in writing to the notification so that the product can be placed on the market and shall inform the other Member States and the Commission thereof.

3. In cases where the competent authority of another Member State raises an objection — for which the reasons must be stated — and should it not be possible for the competent authorities concerned to reach an agreement within the period specified in paragraph 2, the Commission shall take a decision in accordance with the procedure laid down in Article 21.

4. Where the Commission has taken a favourable decision, the competent authority that received the original notification shall give consent in writing to the notification so that the product may be placed on the market and shall inform the other Member States and the Commission thereof.

5. Once a product has received a written consent, it may be used without further notification throughout the Community in so far as the specific conditions of use and the environments and/or geographical areas stipulated in these conditions are strictly adhered to.

6. Member States shall take all necessary measures to ensure that users comply with the conditions of use specified in the written consent.

Article 14

Member States shall take all necessary measures to ensure that products containing, or consisting of, GMOs will be placed on the market only if their labelling and packaging is that specified in the written consent referred to in Articles 12 and 13.

Article 15

Member States may not, on grounds relating to the notification and written consent of a deliberate release under this Directive, prohibit, restrict or impede the placing on the market of products containing, or consisting of, GMOs which comply with the requirements of this Directive.

Article 16

1. Where a Member State has justifiable reasons to consider that a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment, it may provisionally restrict or prohibit the use and/or sale of that product on its territory. It shall immediately inform the Commission and the other Member States of such action and give reasons for its decision.

2. A decision shall be taken on the matter within three months in accordance with the procedure laid down in Article 21.

Article 17

The Commission shall publish in the *Official Journal of the European Communities* a list of all the products receiving final written consent under this Directive. For each product, the GMO or GMOs contained therein and the use or uses shall be clearly specified.

Article 18

1. Member States shall send to the Commission, at the end of each year, a brief factual report on the control of the use of all products placed on the market under this Directive.

2. The Commission shall send to the European Parliament and the Council, every three years, a report on the control by the Member States of the products placed on the market under this Directive.

3. When submitting this report for the first time, the Commission shall at the same time submit a specific report on the operation of this Part of this Directive including an assessment of all its implications.

PART D

Final provisions

Article 19

1. The Commission and the competent authorities shall not divulge to third parties any confidential information notified or exchanged under this Directive and shall protect intellectual property rights relating to the data received.

2. The notifier may indicate the information in the notification submitted under this Directive, the disclosure of which might harm his competitive position, that should therefore be treated as confidential. Verifiable justification must be given in such cases.

3. The competent authority shall decide, after consultation with the notifier, which information will be kept confidential and shall inform the notifier of its decisions.

4. In no case may the following information when submitted according to Articles 5 or 11 be kept confidential:

— description of the GMO or GMOs, name and address of the notifier, purpose of the release and location of release;

— methods and plans for monitoring of the GMO or GMOs and for emergency response;

— the evaluation of foreseeable effects, in particular any pathogenic and/or ecologically disruptive effects.

5. If, for whatever reasons, the notifier withdraws the notification, the competent authorities and the Commission must respect the confidentiality of the information supplied.

Article 20

According to the procedure laid down in Article 21, the Commission shall adapt Annexes II and III to technical progress in particular by amending the notification requirements to take into account the potential hazard of the GMOs.

Article 21

The Commission shall be assisted by a committee composed of the representatives of the Member States and chaired by the representative of the Commission.

The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148 (2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.

If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period of three months from the date of referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 22

1. Member States and the Commission shall meet regularly and exchange information on the experience acquired with regard to the prevention of risks related to the release of GMOs into the environment.

2. Every three years, Member States shall send the Commission a report on the measures taken to implement the provisions of this Directive, the first time being on 1 September 1992.

3. Every three years, the Commission shall publish a summary based on the reports referred to in paragraph 2, the first time being in 1993.

Article 23

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 23 October 1991.

2. Member States shall immediately inform the Commission of all laws, regulations and administrative provisions adopted in implementation of this Directive.

Article 24

This Directive is addressed to the Member States.

Done at Luxembourg, 23 April 1990.

For the Council
The President
A. REYNOLDS

ANNEX I A

TECHNIQUES REFERRED TO IN ARTICLE 2 (2)

PART 1

Techniques of genetic modification referred to in Article 2 (2) (i) are *inter alia:*

(1) recombinant DNA techniques using vector systems as previously covered by Council Recommendation 82/472/EEC (1);

(2) techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation;

(3) cell fusion (including protoplast fusion) or hybridization techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

PART 2

Techniques referred to in Article 2 (2) (ii) which are not considered to result in genetic modification, on condition that they do not involve the use of recombinant DNA molecules or GMOs, are:

(1) *in vitro* fertilization,

(2) conjugation, transduction, transformation or any other natural process,

(3) polyploidy induction.

ANNEX I B

TECHNIQUES REFERRED TO IN ARTICLE 3

Techniques of genetic modification to be excluded from this Directive, on condition that they do not involve the use of GMOs as recipient or parental organisms, are:

(1) mutagenesis,

(2) cell fusion (including protoplast fusion) of plant cells where the resulting organisms can also be produced by traditional breeding methods.

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(1) OJ NO L 213, 21. 7. 1982, p. 15.

COMMISSION DIRECTIVE 94/15/EC

of 15 April 1994

adapting to technical progress for the first time Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (1), and in particular Article 20 thereof,

Whereas Annex II to Directive 90/220/EEC contains the information required to be provided in a notification for a deliberate release of genetically modified organisms (GMOs);

Whereas the information requirements for notifications for a deliberate release of GMOs, as set out in Annex II, are very broad in order to apply to all types of GMOs; whereas some of the information is only applicable or appropriate for specific types of organisms;

Whereas, on the basis of the experience gained with the releases of genetically modified higher plants, it is appropriate to adapt Annex II to technical progress by making provision for a sub-Annex specific to higher plants;

Whereas it is therefore appropriate that Annex II should be divided in two sub-Annexes: Annex II A outlining the information required in the notifications concerning releases of GMOs other than higher plants, and Annex II B outlining the information required in the notifications concerning releases of genetically modified higher plants;

Whereas the measures provided for in this Directive are in accordance with the opinion of the committee provided for in Article 21 of Directive 90/220/EEC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex II to Directive 90/220/EEC is replaced by the Annex hereto.

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 30 June 1994. They shall immediately inform the Commission thereof.

When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

Article 3

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Communities*.

Done at Brussels, 15 April 1994.

For the Commission

Yannis PALEOKRASSAS

Member of the Commission

(1) OJ No L 117, 8. 5. 1990, p. 15.

ANNEX

'ANNEX II

INFORMATION REQUIRED IN THE NOTIFICATION

The notification for a deliberate release referred to in Article 5 and of the placing on the market referred to in Article 11 is to include, as appropriate, the information set out below in the sub-Annexes.

Not all points included will apply to every case It is to be expected that individual notifications will address only the particular subset of considerations which is appropriate to individual situations.

The level of detail required in response to each subset of considerations is also likely to vary according to the nature and scale of the proposed release.

Annex II A applies to releases of all types of genetically modified organisms other than higher plants. Annex II B applies to releases of genetically modified higher plants

The term "higher plants" means plants which belong to the taxonomic groups *Gymnospermae* and *Angiospermae*

ANNEX II A

INFORMATION REQUIRED IN NOTIFICATIONS CONCERNING RELEASES OF GENETICALLY MODIFIED ORGANISMS OTHER THAN HIGHER PLANTS

I. GENERAL INFORMATION

A. Name and address of the notifier (company or institute)

B. Name, qualifications and experience of the responsible scientist(s)

C. Title of the project

II. INFORMATION RELATING TO THE GMO

A. Characteristics of (a) the donor, (b) the recipient or (c) (where appropriate) parental organism(s):

1. scientific name;
2. taxonomy;
3. other names (usual name, strain name, etc.),
4. phenotypic and genetic markers;
5. degree of relatedness between donor and recipient or between parental organisms,
6. description of identification and detection techniques;
7. sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques;
8. description of the geographic distribution and of the natural habitat of the organism including information on natural predators, preys, parasites and competitors, symbionts and hosts,
9. potential for genetic transfer and exchange with other organisms;
10. verification of the genetic stability of the organisms and factors affecting it;
11. pathological, ecological and physiological traits:
    (a) classification of hazard according to existing Community rules concerning the protection of human health and/or the environment;
    (b) generation time in natural ecosystems, sexual and asexual reproductive cycle;
    (c) information on survival, including seasonability and the ability to form survival structures e.g.: seeds, spores or sclerotia;
    (d) pathogenicity: infectivity, toxigenicity, virulence, allergenicity, carrier (vector) of pathogen, possible vectors, host range including non-target organism. Possible activation of latent viruses (proviruses). Ability to colonize other organisms;
    (e) antibiotic resistance, and potential use of these antibiotics in humans and domestic organisms for prophylaxis and therapy;
    (f) involvement in environmental processes: primary production, nutrient turnover, decomposition of organic matter, respiration, etc.
12. Nature of indigenous vectors:
    (a) sequence;
    (b) frequency of mobilization;
    (c) specificity;
    (d) presence of genes which confer resistance.
13. History of previous genetic modifications.

B. Characteristics of the vector:

1. nature and source of the vector;
2. sequence of transposons, vectors and other non-coding genetic segments used to construct the GMO and to make the introduced vector and insert function, in the GMO;

3. frequency of mobilization of inserted vector and/or genetic transfer capabilities and methods of determination;

4. information on the degree to which the vector is limited to the DNA required to perform the intended function.

C. Characteristics of the modified organism:

1. Information relating to the genetic modification:

(a) methods used for the modification;

(b) methods used to construct and introduce the insert(s) into the recipient or to delete a sequence;

(c) description of the insert and/or vector construction;

(d) purity of the insert from any unknown sequence and information on the degree to which the inserted sequence is limited to the DNA required to perform the intended function;

(e) sequence, functional identity and location of the altered/inserted/deleted nucleic acid segment(s) in question with particular reference to any known harmful sequence

2. Information on the final GMO

(a) description of genetic trait(s) or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed;

(b) structure and amount of any vector and/or donor nucleic acid remaining in the final construction of the modified organism;

(c) stability of the organism in terms of genetic traits;

(d) rate and level of expression of the new genetic material. Method and sensitivity of measurement;

(e) activity of the expressed protein(s);

(f) description of identification and detection techniques including techniques for the identification and detection of the inserted sequence and vector;

(g) sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques;

(h) history of previous releases or uses of the GMO

(i) health considerations:

(i) toxic or allergenic effects of the non-viable GMOs and or their metabolic products;

(ii) product hazards;

(iii) comparison of the modified organism to the donor, recipient or (where appropriate) parental organism regarding pathogenicity;

(iv) capacity for colonization;

(v) if the organism is pathogenic to humans who are immunocompetent:

— diseases caused and mechanism of pathogenicity including invasiveness and virulence,
— communicability,
— infective dose,
— host range, possibility of alteration,
— possibility of survival outside of human host,
— presence of vectors or means of dissemination,
— biological stability,
— antibiotic-resistance patterns,
— allergenicity,
— availability of appropriate therapies.

III. INFORMATION RELATING TO THE CONDITIONS OF RELEASE AND THE RECEIVING ENVIRONMENT

A. Information on the release:

1. description of the proposed deliberate release, including the purpose(s) and foreseen products;

2. foreseen dates of the release and time planning of the experiment including frequency and duration of releases;

3. preparation of the site previous to the release;

4. size of the site;

5. method(s) to be used for the release;
6. quantities of GMOs to be released.
7. disturbance on the site (type and method of cultivation, mining, irrigation, or other activities);
8. worker protection measures taken during the release;
9. post-release treatment of the site;
10. techniques foreseen for elimination or inactivition of the GMOs at the end of the experiment;
11. information on, and results of, previous releases of the GMOs, especially at different scales and in different ecosystems.

B. Information on the environment (both on the site and in the wider environment):

1. geographical location and grid reference of the site(s) (in case of notifications under Part C the site(s) of release will be the foreseen areas of use of the product);
2. physical or biological proximity to humans and other significant biota;
3. proximity to significant biotopes or protected areas;
4. size of local population;
5. economic activities of local populations which are based on the natural resources of the area;
6. distance to closest areas protected for drinking water and/or environmental purpose;
7. climatic characteristics of the region(s) likely to be affected;
8. geographical, geological and pedological characteristics;
9. flora and fauna, including crops, livestock and migratory species;
10. description of target and non-target ecosystems likely to be affected;
11. a comparison of the natural habitat of the recipient organism with the proposed site(s) of release;
12. any known planned developments or changes in land use in the region which could influence the environmental impact of the release.

IV. INFORMATION RELATING TO THE INTERACTIONS BETWEEN THE GMOs AND THE ENVIRONMENT

A. Characteristics affecting survival, multiplication and dissemination:

1. biological features which affect survival, multiplication and dispersal;
2. known or predicted environmental conditions which may affect survival, multiplication and dissemination (wind, water, soil, temperature, pH, etc.);
3. sensitivity to specific agents.

B. Interactions with the environment:

1. predicted habitat of the GMOs;
2. studies of the behaviour and characteristics of the GMOs and their ecological impact carried out in simulated natural environments, such as microcosms, growth rooms, greenhouses;
3. genetic transfer capability:
   (a) post-release transfer of genetic material from GMOs into organisms in affected ecosystems;
   (b) post-release transfer of genetic material from indigenous organisms to the GMOs;
4. likelihood of post-release selection leading to the expression of unexpected and/or undesirable traits in the modified organism;
5. measures employed to ensure and to verify genetic stability. Description of genetic traits which may prevent or minimize dispersal of genetic material. Methods to verify genetic stability;
6. routes of biological dispersal, known or potential modes of interaction with the disseminating agent, including inhalation, ingestion, surface contact, burrowing, etc.;
7. description of ecosystems to which the GMOs could be disseminated.

C Potential environmental impact

1 potential for excessive population increase in the environment;

2. competitive advantage of the GMOs in relation to the unmodified recipient or parental organism(s);

3. identification and description of the target organisms;

4. anticipated mechanism and result of interaction between the released GMOs and the target organism;

5. identification and description of non-target organisms which may be affected unwittingly;

6. likelihood of post-release shifts in biological interactions or in host range;

7. known or predicted effects on non-target organisms in the environment, impact on population levels of competitors: preys, hosts, symbionts, predators, parasites and pathogens;

8. known or predicted involvement in biogeochemical processes;

9. other potentially significant interactions with the environment.

V. INFORMATION ON MONITORING, CONTROL, WASTE TREATMENT AND EMERGENCY RESPONSE PLANS

A. Monitoring techniques

1 methods for tracing the GMOs, and for monitoring their effects;

2. specificity (to identify the GMOs, and to distinguish them from the donor, recipient or, where appropriate, the parental organisms), sensitivity and reliability of the monitoring techniques;

3. techniques for detecting transfer of the donated genetic material to other organisms;

4. duration and frequency of the monitoring.

B Control of the release

1. methods and procedures to avoid and/or minimize the spread of the GMOs beyond the site of release or the designated area for use;

2. methods and procedures to protect the site from intrusion by unauthorized individuals;

3. methods and procedures to prevent other organisms from entering the site.

C. Waste treatment:

1. type of waste generated;

2. expected amount of waste;

3. possible risks;

4. description of treatment envisaged.

D. Emergency response plans:

1. methods and procedures for controlling the GMOs in case of unexpected spread;

2. methods for decontamination of the areas affected, e.g. eradication of the GMOs;

3. methods for disposal or sanitation of plants, animals, etc., that were exposed during or after the spread;

4. methods for the isolation of the area affected by the spread;

5. plans for protecting human health and the environment in case of the occurrence of an undesirable effect.

ANNEX II B

INFORMATION REQUIRED IN NOTIFICATIONS CONCERNING RELEASES OF GENETICALLY MODIFIED HIGHER PLANTS (GMHPs) *(GYMNOSPERMAE* AND *ANGIOSPERMAE)*

A. GENERAL INFORMATION

1. Name and address of the notifier (company or institute)
2. Name, qualifications and experience of the responsible scientist(s)
3. Title of the project

B. INFORMATION RELATING TO (A) THE RECIPIENT OR (B) (WHERE APPROPRIATE) PARENTAL PLANTS

1. Complete name:
   (a) family name;
   (b) genus;
   (c) species;
   (d) subspecies;
   (e) cultivar/breeding line;
   (f) common name.
2. (a) Information concerning reproduction:
   (i) mode(s) of reproduction;
   (ii) specific factors affecting reproduction, if any;
   (iii) generation time.
   (b) Sexual compatibility with other cultivated or wild plant species.
3. Survivability:
   (a) ability to form structures for survival or dormancy;
   (b) specific factors affecting survivability, if any.
4. Dissemination:
   (a) ways and extent of dissemination;
   (b) specific factors affecting dissemination, if any.
5. Geographical distribution of the plant.
6. In the case of plant species not normally grown in the Member State(s), description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts.
7. Potentially significant interactions of the plant with organisms other than plants in the ecosystem where it is usually grown, including information on toxic effects on humans, animals and other organisms.

C. INFORMATION RELATING TO THE GENETIC MODIFICATION

1. Description of the methods used for the genetic modification.
2. Nature and source of the vector used.
3. Size, source (name of donor organism(s) and intended function of each constituent fragment of the region intended for insertion.

D. INFORMATION RELATING TO THE GENETICALLY MODIFIED PLANT

1. Description of the trait(s) and characteristics which have been introduced or modified.
2. Information on the sequences actually inserted/deleted:
   (a) size and structure of the insert and methods used for its characterization, including information on any parts of the vector introduced in the GMHP or any carrier or foreign DNA remaining in the GMHP;
   (b) in case of deletion, size and function of the deleted region(s);
   (c) location of the insert in the plant cells (integrated in the chromosome, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its determination;
   (d) copy number of the insert.
3. Information on the expression of the insert:
   (a) information on the expression of the insert and methods used for its characterization;
   (b) parts of the plant where the insert is expressed (e.g. roots, stem, pollen etc.)

4. Information on how the genetically modified plant differs from the recipient plant in :

   (a) mode(s) and/or rate of reproduction ;

   (b) dissemination ;

   (c) survivability.

5. Genetic stability of the insert.

6. Potential for transfer of genetic material from the genetically modified plants to other organisms.

7. Information on any toxic or harmful effects on human health and the environment, arising from the genetic modification.

8. Mechanism of interaction between the genetically modified plant and target organisms (if applicable).

9. Potentially significant interactions with non-target organisms.

10. Description of detection and identification techniques for the genetically modified plant.

11. Information about previous releases of the genetically modified plant, if applicable.

E. INFORMATION RELATING TO THE SITE OF RELEASE (ONLY FOR NOTIFICATIONS SUBMITTED PURSUANT TO ARTICLE 5)

1. Location and size of the release site(s).

2. Description of the release site ecosystem, including climate, flora and fauna.

3. Presence of sexually compatible wild relatives or cultivated plant species.

4. Proximity to officially recognized biotopes or protected areas which may be affected.

F. INFORMATION RELATING TO THE RELEASE (ONLY FOR NOTIFICATIONS SUBMITTED PURSUANT TO ARTICLE 5)

1. Purpose of the release.

2. Foreseen date(s) and duration of the release.

3. Method by which the genetically modified plants will be released.

4. Method for preparing and managing the release site, prior to, during and post-release, including cultivation practices and harvesting methods.

5. Approximate number of plants (or plants per m^2).

G. INFORMATION ON CONTROL, MONITORING, POST-RELEASE AND WASTE TREATMENT PLANS (ONLY FOR NOTIFICATIONS SUBMITTED PURSUANT TO ARTICLE 5)

1. Any precautions taken :

   (a) distance(s) from sexually compatible plant species ;

   (b) any measures to minimize/prevent pollen or seed dispersal.

2. Description of methods for post-release treatment of the site.

3. Description of post-release treatment methods for the genetically modified plant material including wastes.

4. Description of monitoring plans and techniques.

5. Description of any emergency plans.

H. INFORMATION ON THE POTENTIAL ENVIRONMENTAL IMPACT FROM THE RELEASE OF THE GENETICALLY MODIFIED PLANTS

1. Likelihood of the GMHP becoming more persistent than the recipient or parental plants in agricultural habitats or more invasive in natural habitats.

2. Any selective advantage or disadvantage conferred to other sexually compatible plants species, which may result from genetic transfer from the genetically modified plant.

3. Potential environmental impact of the interaction between the genetically modified plant and target organisms (if applicable).

4. Possible environmental impact resulting from potential interactions with non-target organisms.

ANNEX III

ADDITIONAL INFORMATION REQUIRED IN THE CASE OF NOTIFICATION FOR PLACING ON THE MARKET

A. The following information shall be provided in the notification for placing on the market of products, in addition to that of Annex II:

1. name of the product and names of GMOs contained therein;
2. name of the manufacturer or distributor and his address in the Community;
3. specificity of the product, exact conditions of use including, when appropriate, the type of environment and/or the geographical area(s) of the Community for which the product is suited;
4. type of expected use: industry, agriculture and skilled trades, consumer use by public at large.

B. The following information shall be provided, when relevant, in addition to that of point A, in accordance with Article 11 of this Directive:

1. measures to take in case of unintended release or misuse;
2. specific instructions or recommendations for storage and handling;
3. estimated production in and/or imports to the Community;
4. proposed packaging. This must be appropriate so as to avoid unintended release of the GMOs during storage, or at a later stage;
5. proposed labelling. This must include, at least in summarized form, the information referred to in points A. 1, A. 2, A. 3, B. 1 and B. 2.

XI/401/91-Rev.2

COUNCIL DIRECTIVE 90/220/EEC ON THE DELIBERATE RELEASE OF GENETICALLY MODIFIED ORGANISMS

EXPLANATORY NOTES
(to be read together with the text of the Directive)

EXPLANATORY NOTES FOR COUNCIL DIRECTIVE 90/220/EEC ON THE DELIBERATE RELEASE INTO THE ENVIRONMENT OF GENETICALLY MODIFIED ORGANISMS

Preface

On 23.04.1990, the Council of the European Communities adopted legislation in the form of Directive 90/220/EEC laying down the procedure and conditions for obtaining the consent to release genetically modified organisms into the environment in any part of the European Community. EC Member States must implement this Community legislation at the latest by 23 October 1991.

The legal text of the Directive is published in all the Community languages in the Official Journal of the European Communities, no. L 117, dated 8.5.1990 and is available free of charge. (The Italian and Greek texts were subsequently corrected in the OJ L 7, 10.1.91 and other linguistic corrections are still to be published).

These Explanatory Notes offer practical guidance to assist in the understanding and implementation of the Directive. Although the guidance is based on legal requirements, it is not intended to be an authoritative interpretation of the law; such interpretation can only be made by the European Court of Justice.

Preamble

The preamble to the Article of the Directive summarises the contents of the Articles and highlights the significant points. It is the Articles that lay down the legal requirements but the preamble can help clarify and interpret the main body of the legal text.

The legal basis of the Directive is Article 100 a of the Treaty establishing the European Economic Community, which states , amongst others, the following:

"....The Council shall, acting by a qualified majority on a proposal from the Commission in cooperation with the European Parliament and after consulting the Economic and Social Committee, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.

The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection.

If, after the adoption of a harmonization measure by the Council acting by a qualified majority, a Member State deems it necessary to apply national provisions on grounds of major needs referred to in Article 36, or relating to protection of the environment or the working environment, it shall notify the Commission of these provisions.

The Commission shall confirm the provisions involved after having verified that they are not a means of arbitrary discrimination or a disguised restriction on trade between Member States.

By way of derogation from the procedure laid down in Articles 169 and 170, the Commission or any Member State may bring the matter directly before the Court of Justice if it considers that another Member State is making improper use of the powers provided for in this Article."

Article 1

The dual objective of this Directive is to provide a harmonised regulatory framework for all releases of GMOs into the environment (for both experimental and commercial purposes), and to provide for the protection of human health and the environment. Transport of GMOs is excluded from the scope of this Directive and the Commission is preparing a seperate proposal to cover this aspect.

Article 2

(1) The definition of "organism" covers : micro-organisms, including viruses and viroids; plants and animals; including ova, seeds, pollen, cell cultures and tissue cultures from plants and animals. This definition does not cover naked r DNA and naked r-plasmids.

(3) The intentional introduction into the environment means the introduction by whatever means, directly or indirectly, by using, storing, disposing, or making available to a third party, of a GMO or a combination of GMOs. Further guidance on the interpretation of "storing" and "disposing" is under preparation.

(5) Despite the wide definition of "placing on the market", there are carefully considered cases in certain circumstances where a GMO-containing product within the scope of 90/220/EEC which is supplied or made available to a third party can nonetheless be considered as not requiring approval under Part C of the Directive. One such is the case of GMOs specifically developed for a user on a bilateral agreement between a supplier and a user, provided its use in research is subsequently notified under Part B of this Directive. Further examples are given in the Guidance Document for the interpretation of the term "Placing on the Market" (Document XI/57/92).

Article 3

Certain GMOs are excluded from the scope of this Directive.

Article 4

Member States have the obligation both to take measures themselves (legal, administrative and practical) and to lay down measures that need to be taken by those carrying out a GMO release of any kind in order to avoid adverse effects on human health and the environment. The measures referred to cover both general and specific measures, and can be before, during and after a release, as appropriate.

Competent authorities responsible for GMO releases had to be designated by Member States at the latest by 23.10.1991. Annex I gives details of the authorities so far formally designated in the Community under this Directive.

The other control measures mentioned in this Article could include, where this is consistent with national practice, arrangements for consultation with a workplace biological safety committee or other appropriate bodies in preparing the evaluation mentioned in Article 5(2)(b).

Note: Articles 5, 6, 7, 8 and 9 (part B) refer to releases of GMOs for research and development purposes or for any other purposes than for placing on the market.

Article 5

Notification of proposals to carry out a GMO release must be submitted prior to the release to the competent authority appointed for this purpose in the Member State where the release is planned. Annex I lists, for information, the authorities so far formally notified to the Commission. Potential notifiers need to identify directly who the competent authorities are in the Member States not mentioned in this list.

Responsibility for providing the required information on the proposed release lies with the person who will carry out the release. In practise, the "person" will generally be a body corporate, e.g. a company, University or Institute. As well as the information indicated in Annex II of the Directive, a statement evaluating impact and risks posed by the GMO(s) to human health or the environment must be included in the dossier. This will be an element assisting the authorities in making their environmental risk assessment of the proposed release.

In order to facilitate the procedures and reduce possible costs, the authorities can accept that a number of releases falling within the same experimental programme in a specified period (e.g. one year) can be treated as one notification. This does not alter the requirements for specific information on the different sites or the different GMOs, but can simplify the procedures.

Applicants are encouraged to refer to data from their own previous releases or those of other notifiers. It is important that unnecessary animal experimentation is avoided and that Directive 86/609/EEC of 24.11.1986 on the protection of animals used for experimental and other scientific purpose is adhered to. Animal experimentation that may be required in order to supply data under this Directive should be minimised as far as possible by avoiding repetition of experiments. Maximum use of available data should be made.

Even after the notification has been submitted, or even approved, the notifier still has the responsibility to provide to the authorities any additional important information as specified, and take additional protection measures as necessary.

Article 6

A notifier may only proceed with the release after a written consent has been given by the competent authority in the country where the experimental release will take place. This is given within the specified period after that authority has examined the application, made its risk evaluation, and noted any comments from other authorities or interested parties. The authority retains the possibility to come back to the notifier subsequent to an approval if new significant information related to risks becomes available.

Article 7

Member States have the possibility to make wider consultations before giving approval for a particular release under Part B of the Directive, provided that confidentiality is respected as outlined in Article 19.

Article 8

In order to help authorities approve subsequent releases and to have a feedback on their assessment, relevant information resulting from the release concerning risks and indicating future intentions of notifying the GMO as a product must be communicated to the authorities.

Article 9

Member States authorities in countries other than the one where the release is taking place will have the opportunity to make relevant observations within a 30-day period on the basis of summary information provided. These observations are not binding in any way. The competent authorities approving the release must inform the authorities of other Member States and the Commission of their final decision.

To facilitate the exchange of information on experimental releases between Member States, a Summary Notification Information Format has been established as foreseen by the procedure of Article 21, and was adopted as Council Decision 91/596/EEC on 4.11.91 (OJ L 322, 23.11.91);

Note: Articles 10, 11, 12, 13, 14, 15, 16, 17 and 18 (part C) refer to releases of GMOs resulting from the marketing of any product containing or consisting of GMOs.

Article 10

In order to be placed on the market, a GMO-containing product must have received consent for testing first (as foreseen under Part B), or must have undergone a risk assessment based on the elements outlined in Part B, and must have received clearance both as regards its environmental impact, as foreseen under Part C of this Directive, and as regards aspects which may be covered by specific Community product legislation. The clearance under Part C of this Directive for placing on the market of products consisting of or containing GMOs, concerns aspects relating to the potential risks to humans, plants, animals and the environment connected with the release of these products.

It is possible for certain GMO-containing products not to be covered under Part C of this Directive, if it is decided under the procedure foreseen under Article 21 of this Directive that other Community legislation in force provides for a specific environmental risk assessment similar to that laid down in this Directive.

A Commission decision (91/274/EEC taken in accordance with the procedure of Article 21 established there is currently no such Community legislation in force (OJ L 135, 30.5.91)

Article 11

Before a release is made by placing a product on the market, a written consent must be obtained by the importer or manufacturer of the product, issued according to the Community approval procedures outlined under Article 13. This consent may have specific conditions attached to it.

The importer or manufacturer will deal only with one competent authority in a Member State where the product will be marketed for the first time. This authority, chosen by the notifier, will act as a "gateway" to the system, will receive the information submitted by the notifier, and will be responsible for issuing the final consent.

The information to be submitted is indicated in Annexes II and III, and reference must also be made to data obtained in releases carried out by the notifier either inside or outside the Community. Applicants are encouraged to refer to relevant data available from their own previous releases or those from other notifiers. This may in some cases, have the positive effect of reducing the necessity for animal experimentation. It is important that unnecessary animal experiments are avoided and that Directive 86/609/EEC of 24.11.86 on the protection of animals used for experimental and other scientific purposes is adhered to. Animal experimentation that may be required in order to supply data under this Directive should minimised as far as possible by avoiding repetition of experiments. Maximum use of available data should be made.

Even after the notification has been submitted, or even approved, the notifier still has the responsibility to provide to the authorities any additional important information as specified, and take additional protection measures as necessary.

Article 12

The competent authority receiving the notification is responsible for carrying out the main environmental risk assessment within a maximum 90 day period. Any period of time during which the competent authority is awaiting further information which it is has requested from the notifier is not included in the 90 days. If the assessment is satisfactory, the authority then forwards the application to the Commission with a favourable opinion for consent. The dossier forwarded must include a summary of the notification; the format of this summary has been established as foreseen, according to the procedures of Article 21, and has been adopted as Commission Decision 92/146/EEC of 11.2.92 (OJ L 60, 5.3.92).

Article 13

The Commission is responsible for ensuring that the Community-wide consultation procedure takes place effectively and efficiently. The consultation of the other Member States is made without a meeting, by simply circulating the dossier to the competent authorities, with the necessary confidentiality precautions. A consent valid for the whole Community is given to the applicant by the main authority dealing with the dossier, if within the period of 60 days no insurmountable difficulties or objections are raised.

If a competent authority of a Member State indicates within the specified period that it does not wish consent to be given for that particular release, then a meeting of the Article 21 Committee will be called immediately and a vote on the matter shall be taken as foreseen by Article 21. This will be done as soon as possible, and no later than 3 months from the expiry of the period laid down in Article 13(2).

The consent is issued to the applicant following a favourable vote in the Committee by qualified majority. No further notification is required as regards matters within the scope of the Directive.

The consent may mention specific conditions, and Member States have an obligation to ensure that these conditions are adhered to.

If products receive environmental safety clearance in some Member States before 23 October 1991, and are marketed by that date, they can continue being on the market of those Member States after October 23, but they will need to be approved by the Community procedures of Directive 90/220/EEC before being placed on the market of other Member States.

Article 14

Any conditions of labelling and packaging specified on the consent need to be adhered to, and Member States have the obligation to ensure that this is so.

Article 15

The scope of this Directive covers only the aspects of the product relating to safety, the environment and human health, and is as far as this aspect is concerned, no Member State can take action to prohibit, restrict or impede the release of a GMO-containing product except as provided for in Article 16. Compliance with other regulatory requirements (e.g. for appearance, efficiency, acceptability, quality, etc.) is outside the scope of this Directive and this Article.

Article 16

This "safeguard clause" in the Directive is intended to deal with emergency cases where new data or evidence concerning environmental safety becomes available after a product has been given clearance on these aspects. The sale or use of products can be provisionally restricted by a Member State, but within three months a binding decision must be taken at Community level on the validity or otherwise of this unilateral action.

Article 17

It is envisaged that publication in the Official Journal of products approved will be done periodically, every three or six months, as necessary.

Article 18

The first report from Member States on the control of the use of products placed on the market is to be sent to the Commission at the end of 1992 and the Commission's own report to the EP and the Council will be sent for the first time in 1995. Suggested outlines for the Member States reports will be provided.

Article 19

The confidentiality provisions outlined in this Article are of extreme importance. The Commission has put into place, together with the Member State competent authorities, a scheme with specific procedures, requirements and measures to ensure the protection of confidential information at all levels (Ref: Doc. XI/140/92-fin).

The Commission has the responsibility to ensure that the confidentiality provisions are adhered to and absence of suitable measures in Member States will be considered as an infringement. One practical effect of this will be that confidential information will not be received by that Member State from the Commission or other Member States.

At the same time, it is also important that certain information is not kept confidential as outlined in Article 19.4. The Commission has drawn up, together with the Member State competent authorities, guidance concerning this aspect (Document XI/621/91-fin).

Article 20

As new technical information becomes available, it is foreseen that some of the annexes will be adapted to technical progress.

Article 21

The Committee foreseen has several important functions, as outlined in the Directive. It will be chaired by the Commission (DG XI) and will operate according to the internal rules it adopted at its first meeting on 25 March 1991 in Brussels (Document XI/88/91).

In order for Member States to participate fully in this Committee after the implementation date of 23.10.1991, they must have transposed all aspects of this Directive into national law.

The votes of Member States are weighted as follows: Belgium 5, Denmark 3, Germany 10, Greece 5, Spain 8, France 10, Ireland 3, Italy 10, Luxembourg 2, Netherlands 5, Portugal 5 and United Kingdom 10.

To be adopted, a proposal must receive 54 votes in favour.

Article 22

Regular meetings organised by the Commission of the Committee of Competent Authorities will ensure that information and experience is exchanged.

Article 23

In order to be implemented in a Member State, the Directive has to be transposed in its entirety and in all the regions of a Member State. Member States which have not fully transposed the Directive will be in infringement of the Directive. One practical consequence may be that they will be unable to participate in the Community consultation procedures foreseen in the Directive.

If a Member State does not implement fully or correctly the Directive, the Commission will take the necessary steps to start infringement procedures as foreseen under Article 169 of the Treaty.

Member States have to officially inform the Commission of their legislation as soon as it is adopted. Once the Commission has been informed of legislative measures taken, it will examine them to ensure confirmity with the Directive. If there is no conformity Member States will be notified and asked to take the necessary measures. If they do not comply, infringement procedures will be started.

Article 24

The Directive is a piece of legislation addressed only to the Member States governments who in turn are responsible for taking the necessary action for implemetation.

COMPETENT AUTHORITIES FORMALLY APPOINTED BY MEMBER STATES TO BE RESPONSIBLE FOR THE IMPLEMENTATION OF DIRECTIVE 90/220/EEC

DENMARK

The Ministry of Environment
Slotsholmsgade 12
DK - 1216 KOBENHAVN K

FEDERAL REPUBLIC OF GERMANY

Main Competent Authority for handling release notifications
Bundesgesundheitsamt
Thielallee 88-92
D - 1000 BERLIN 33

Authorities Cooperating with the Main Competent Authority above
Umweltbundesamt
Bismarckplatz 1
D - 1000 BERLIN 33

Biologische Bundesanstalt für Land- und Forstwirtschaft
Messeweg 11-12
D - 330 BRAUNSCHWEIG

Bundesforschungsanstalt für Viruskrankheiten der Tiere
Paul-Ehrlich-Str. 28
D - 7400 TUBINGEN 1

Overall National Authority responsible for implementation of the Directive
Bundesministerium für Gesundheit
Referat 353
D - 5000 BONN 2

FRANCE

Ministère de l'Environnement
DEPPR
14, Bd du Général Leclerc
F - 92524 NEUILLY-SUR-SEINE

Ministère de l'Agriculture
DGAL
175, rue du Chevaleret
F - 75013 PARIS

SPAIN (provisional appointment)

Secretarià de Estado para las Politicas de Agues
y Medio Ambiente
Paseo de la Castellana 67
E - 28071 MADRID

ITALY (provisional appointment)

Ministero della Sanità
Via Sierra Nevada 60
I-00144 ROMA

NETHERLANDS

Ministry of Housing, Planning and Environment Protection
Directorate General for Environment Protection
Postbus 450
NL - 2260 MB LEIDSCHENDAM

PORTUGAL

Direcção Geral Qualidade Ambiente
Rua Século 51-1°
P - 1200 LISBOA

UNITED KINGDOM

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Rommey House
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UK - LONDON SW1 3P4

Health and Safety Executive
Baynards House
1, Chepstow Place
UK - LONDON W2 4TF

BELGIUM (Provisional appointment)

National Authorities
Ministère de la Santé publique et de l'Environnement
Service d'Inspection de la Pharmacie
Service d'Inspection des Denrées alimentaires
Institut d'Expertise vétérinaire

Ministère de l'Agriculture
Service d'Inspection des Matières Premières
Manhattan Center
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Flemish Region
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Wallonian Region
Direction générale des Ressources naturelles
et de l'Environnement
Division de la Prévention des Pollutions
Avenue Albert I, 187
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Brussels-Capital Region
Institut bruxellois pour la gestion de
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Contact Point/Coordination:
Institute of Hygiene and Epidemiology
Biosafety rDNA and Biotechnology
J. Wytsmanstraat 14
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II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 15 April 1994

amending Council Decision 91/596/EEC concerning the summary notification information format referred to in Article 9 of Council Directive 90/220/EEC

(94/211/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (1), and in particular Article 9 thereof,

Whereas the competent authorities appointed by the Member States have to send to the Commission a summary of each notification received under Part B of Directive 90/220/EEC;

Whereas, in consequence, the Council established, by Decision 91/596/EEC (2), the format of this summary, to be used for the release of any type of genetically modified organism (GMO);

Whereas as a result of experience, and given that different information is notified in relation to specific types of GMOs, a revised format is necessary;

Whereas Decision 91/596/EEC should therefore be amended by subdividing the summary notification format into two parts: Part 1 to be used for releases of genetically modified higher plants and Part 2 to be used for releases of any other GMO;

Whereas the measures provided for in this Decision are in accordance with the opinion of the committee provided for in Article 21 of Directive 90/220/EEC,

HAS ADOPTED THIS DECISION:

Article 1

The Annex to Decision 91/596/EEC is replaced by the Annex hereto.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 15 April 1994.

For the Commission

Yannis PALEOKRASSAS

Member of the Commission

(1) OJ No L 117, 8. 5. 1990, p. 15.
(2) OJ No L 322, 22. 11. 1991, p. 1.

ANNEX

PART 1

SUMMARY NOTIFICATION INFORMATION FORMAT FOR RELEASES OF GENETICALLY MODIFIED HIGHER PLANTS *(ANGIOSPERMAE* AND *GYMNOSPERMAE)*

(in accordance with Article 9 of Directive 90/220/EEC)

Introduction

The Summary Notification Information Format for genetically modified higher plant releases, has been established for the purposes and according to the procedures envisaged by Article 9 of Directive 90/220/EEC.

It is recognized that the Summary Notification Information Format for genetically modified higher plant releases is not designed to contain all the information required for carrying out an environmental risk assessment. The space provided after each question is not indicative of the depth of the information required for the purposes of the Summary Notification Information Format.

A. GENERAL INFORMATION

1. **Details of notification**

Notification number: .....

Date of acknowledgment of notification: .....

Title of the project: .....

.....

Proposed period of release: .....

2. Notifier

Name of institute or company: .....

.....

3. **Is the same GMPt release planned elsewhere in the Community (in conformity with Article 5 (1))?**

Yes ☐ No ☐ Not known ☐

If *yes*, insert the country code(s) ☐ ☐ ☐ .....

4. **Has the same GMPt been notified for release elsewhere in the Community by the same notifier?**

Yes ☐ No ☐

If *yes*, notification number: .....

B. INFORMATION ON THE GENETICALLY MODIFIED PLANT

1. **Complete name of the recipient or parental plant**

(a) family name
(b) genus
(c) species
(d) subspecies
(e) cultivar/breeding line
(f) common name

2. **Description of the traits and characteristics which have been introduced or modified, including marker genes and previous modifications**

.....

.....

.....

.....

3. **Type of the genetic modification:**

(a) Insertion of genetic material ☐
(b) Deletion of genetic material ☐
(c) Base substitution ☐
(d) Cell fusion ☐
(e) Other, please specify ☐

4. In the case of insertion of genetic material, give the source and intended function of each constituent fragment of the region to be inserted

5. In the case of deletion of genetic material, give information on the function of the deleted sequences

6. Brief description of the method used for the genetic modification

C. INFORMATION RELATING TO THE EXPERIMENTAL RELEASE

1. Purpose of the release

2. Geographical location of the release site

3. Size of the site (m^2)

PART 2

SUMMARY NOTIFICATION INFORMATION FORMAT FOR RELEASES OF GENETICALLY MODIFIED ORGANISMS OTHER THAN HIGHER PLANTS

(in accordance with Article 9 of Directive 90/220/EEC)

Introduction

The Summary Notification Information Format has been established for the purposes and according to the procedures envisaged by Article 9 of Directive 90/220/EEC.

It is recognized that the Summary Notification Information Format is not designed to contain all the information required for carrying out an environmental risk assessment in the detail necessary for such an assessment. The information entered should, however, adequately reflect (in a condensed form) the information submitted to the competent authority according to Articles 5 and 6 of Directive 90/220/EEC under the conditions specified in the preface to Annex II. The space provided after each question is not indicative of the depth of the information required for the purposes of the Summary Notification Information Format.

D. Summary of the potential environmental impact from the release of the GMPts

E. Brief description of any measures taken for the management of risks

GENERAL INFORMATION

1. Details of notification

Member State of notification : .....

Notification number : .....

Date of acknowledgment of notification : .....

Title of the project : .....

.....

Proposed period of release : .....

2. Notifier

Name of institution or company : .....

.....

3. GMO characterization

(a) Indicate whether the GMO is a :

viroid ☐

RNA virus ☐

DNA virus ☐

bacterium ☐

fungus ☐

animal ☐

other, please specify ☐

.....

.....

(b) Identity of the GMO :

.....

.....

4. **Is the same GMO release planned elsewhere in the Community (in conformity with Article 5 (1)) ?**

Yes ☐ No ☐ Not known ☐

If *yes*, insert the country code(s) ☐ ☐ ☐ .....

5. **Has the same GMO been notified for release elsewhere in the Community by the same notifier ?**

Yes ☐ No ☐

If *yes* :

— Member State of notification : .....

— Notification number : .....

INFORMATION RELATING TO ANNEX II

A. Information relating to the recipient or parental organisms from which the GMO is derived

1. *Indicate whether the recipient or parental organism is a:*

viroid ☐
RNA virus ☐
DNA virus ☐
bacterium ☐
fungus ☐
animal ☐
other, please specify ☐

.....

.....

2. *Complete name*

(i) order and/or higher taxon (for animals)
(ii) genus
(iii) species
(iv) subspecies
(v) strain
(vi) pathovar (biotype, ecotype, race, etc.)
(vii) common name

3. *Geographical distribution of the organism*

(a) Indigenous to the country where the notification is made:

Yes ☐ No ☐ Not known ☐

(b) Indigenous to other EC countries:

(i) Yes ☐

If *yes*, indicate the type of ecosystem in which it is found:

Atlantic ☐ Mediterranean ☐
Arctic ☐ Continental ☐

(ii) No ☐ Not known ☐

(c) Is it *regularly used* in the country where the notification is made?

Yes ☐ No ☐

(d) Is is *regularly kept* in the country where the notification is made?

Yes ☐ No ☐

4. *Natural habitat of the organism*

M (a) If the organism is a microorganism

water ☐
soil, free-living ☐
soil in association with plant-root systems ☐
in association with plant leaf/stem systems ☐
in association with animals ☐
other (specify) ☐

A (b) If the organism is an animal:

natural habitat or usual agroecosystem:

.....

.....

.....

5. (a) *Detection techniques*

.....

.....

(b) *Identification techniques*

.....

.....

6. *Is the recipient organism classified under existing Community rules relating to the protection of human health and/or the environment?*

Yes ☐ No ☐

If *yes*, specify: .....

7. *Is the recipient organism pathogenic or harmful in any other way (including its extracellular products), either living or dead?*

Yes ☐ No ☐

If *yes*:

(a) to which of the following organisms:

humans ☐
animals ☐
plants ☐

(b) give the relevant information specified under Annex II, point II.(A)(11)(d)

.....

.....

.....

8. *Information concerning reproduction:*

(a) Generation time in natural ecosystems:

.....

(b) Generation time in the ecosystem where the release will take place:

.....

(c) Way of reproduction:

Sexual ☐ Asexual ☐

(d) Factors affecting reproduction:

.....

.....

9. *Survivability*

(a) Ability to form structures enhancing survival or dormancy:

(i) endospores ☐
(ii) cysts ☐
(iii) sclerotia ☐
(iv) asexual spores (fungi) ☐
(v) sexual spores (fungi) ☐
(vi) eggs ☐
(vii) pupae ☐
(viii) larvae ☐
(ix) other, please specify ☐

.....

(b) Relevant factors affecting survivability:

.....

.....

10. (a) *Ways of dissemination*

.....

.....

(b) *Factors affecting dissemination*

.....

.....

11. ***Previous genetic modifications of the recipient or parental organism already notified for release in the country where the notification is made (give notification numbers)***

.....

.....

.....

B. Information relating to the genetic modification

1. *Type of the genetic modification*

(i) Insertion of genetic material ☐
(ii) Deletion of genetic material ☐
(iii) Base substitution ☐
(iv) Cell fusion ☐
(v) Other, please specify ☐

.....

2. *Intended result of the genetic modification*

.....

.....

.....

3. (a) *Has a vector been used in the process of modification?*

Yes ☐ No ☐

If *no*, go straight to question 5.

(b) If *yes*, is the vector wholly or partially present in the modified organism?

Yes ☐ No ☐

If *no*, go straight to question 5.

4. *If the ansuer to 3 (b) is* yes, *supply the following information:*

(a) Type of vector

plasmid ☐
bacteriophage ☐
virus ☐
cosmid ☐
phasmid ☐
transposable element ☐
other, please specify ☐

.....

.....

(b) Identity of the vector

.....

.....

(c) Host range of the vector

.....

.....

(d) Presence in the vector of sequences giving a selectable or identifiable phenotype

	Yes	No
Antibiotic resistance	☐	☐
Heavy metal resistance	☐	☐
Other, specify	☐	☐

(e) Constituent fragments of the vector

(f) Method for introducing the vector into the recipient organism

(i) transformation ☐
(ii) electroporation ☐
(iii) macroinjection ☐
(iv) microinjection ☐
(v) infection ☐
(vi) other, please specify ☐

5. *If the answer to question B.3 (a) and (b) is* no, *what was the method used to introduce the insert into the recipient/parental cell?*

(i) transformation ☐
(ii) microinjection ☐
(iii) microencapsulation ☐
(iv) macroinjection ☐
(v) other, please specify ☐

6. *Information on the insert*

(a) Composition of the insert

(b) Source of each constituent part of the insert

(c) Intended function of each constituent part of the insert in the GMO

(d) Location of the insert in the host organism

— on a free plasmid ☐

— integrated in the chromosome ☐

— other, please specify ☐

(e) Does the insert contain parts whose product or function are not known?

Yes ☐ No ☐

If *yes*, please specify: .....

C. Information on the organism(s) from which the insert is derived (Donor)

1. *Indicate whether it is a:*

viroid ☐

RNA virus ☐

DNA virus ☐

bacterium ☐

fungus ☐

plant ☐

animal ☐

other, please specify ☐

2. *Complete name*

(i) order and/or higher taxon (for animals)

(ii) family name (for plants)

(iii) genus

(iv) species

(v) subspecies

(vi) strain

(vii) cultivar/breeding line

(viii) pathovar

(ix) common name

3. *Is the organism pathogenic or harmful in any other way (including its extracellular products), either living or dead?*

Yes ☐ No ☐ Not known ☐

If *yes*, specify the following:

(a) to which of the following organisms?

humans ☐

animals ☐

plants ☐

(b) are the donated sequences involved in any way to the pathogenic or harmful properties of the organism?

Yes ☐ No ☐ Not known ☐

If *yes*, give the relevant information under Annex II, II A, 11 d:

---

4. *Is the donor organism classified under existing Community rules relating to the protection of human health and the environment?*

Yes ☐ No ☐

If *yes*, please specify:

---

5. *Do the donor and recipient organism exchange genetic material naturally?*

Yes ☐ No ☐ Not known ☐

D. Information relating to the genetically modified organism

1. *Genetic traits and phenotypic characteristics of the recipient or parental organism which have been changed as a result of the genetic modification.*

(a) Is the GMO different from the recipient as far as *survivability* is concerned?

Yes ☐ No ☐ Not known ☐

If *yes*, please specify

(b) Is the GMO in any way different from the recipient as far as mode and/or rate of *reproduction* is concerned?

Yes ☐ No ☐ Not known ☐

If *yes*, please specify:

(c) Is the GMO in any way different from the recipient as far as *dissemination* is concerned?

Yes ☐ No ☐ Not known ☐

If *yes*, please specify:

2. *Genetic stability of the genetically modified organism*

3. *Is the GMO pathogenic or harmful in any other way (including its extracellular products), either living or dead?*

Yes ☐ No ☐ Not known ☐

If *yes*,

(a) to which of the following organisms?:

humans ☐

animals ☐

plants ☐

(b) give the relevant information specified under Annex II, point II (A) (11) (d) and II (C) (2) (i)

4. *Description of identification and detection methods*

(a) Techniques used to detect the GMO in the environment

(b) Techniques used to identify the GMO

E. Information relating to the release

1. *Purpose of the release*

2. *Is the site of the release different from the natural habitat or from the ecosystem in which the recipient organism is regularly used, kept or found?*

Yes ☐ No ☐

If *yes*, please specify: .....

3. *Information concerning the release and the surrounding area*

(a) Geographical location (administrative region and where appropriate grid reference):

(b) Size of the site (m^2):

(i) actual release site (m^2):

(ii) wider release area (m^2):

(c) Proximity to internationally recognized biotopes or protected areas (including drinking water reservoirs), which could be affected:

(d) Flora and fauna including crops, livestock and migratory species which may potentially interact with the GMO:

4. *Method and amount of release*

(a) Quantities of GMOs to be released:

(b) Duration of the operation:

(c) Methods and procedures to avoid and/or minimize the spread of the GMOs beyond the site of the release:

F. Interactions of the GMO with the environment and potential impact on the environment

1. *Complete name of target organisms*

(i) order and/or higher taxon (for animals)

(ii) family name (for plants)

(iii) genus

(iv) species

(v) subspecies

(vi) strain

(vii) cultivar

(viii) pathovar

(ix) common name

2. *Anticipated mechanism and result of interaction between the released GMOs and the target organism*

3. *Other potentially significant interactions with other organisms in the environment*

4. *Is post-release selection for the GMO likely to occur?*

Yes ☐ No ☐ Not known ☐

If *yes*, give details: .....

5. *Types of ecosystems to which the GMO could be disseminated from the site of release and in which it could become established*

6. *Complete name of non-target organisms which may be effected unwittingly*

(i) order and/or higher taxon (for animals)

(ii) family name (for plants)

(iii) genus

(iv) species

(v) subspecies

(vi) strain

(vii) cultivar

(viii) pathovar

(ix) common name

7. *Likelihood of genetic exchange* in vivo

(a) from the GMO to other organisms in the release ecosystem:

(b) from other organisms to the GMO:

8. *Give references to relevant results from studies of the behaviour and characteristic of the GMO and its ecological impact carried out in simulated natural environments (e.g. microcosms, etc.):*

G. Information relating to monitoring

1. *Methods for monitoring the GMOs*

2. *Methods for monitoring ecosystem effects*

3. *Methods for detecting transfer of the donated genetic material from the GMO to other organisms*

4. *Spatial extent of the monitoring area (m²)*

5 *Duration of the monitoring*

6. *Frequency of the monitoring*

H. Information on post-release and waste treatment

1. *Post-release treatment of the site*

2. *Post-release treatment of the GMOs*

3. (a) *Type and amount of waste generated*

(b) *Treatments of waste*

I. Information on emergency response plans

1. *Methods and procedures for controlling GMOs in case of unexpected spread*

2. *Methods for decontamination of the areas affected*

3. *Methods for disposal or sanitation of plants, animals, soils etc that were exposed during or after the spread*

4. *Plans for protecting human health and the environment in case of the occurence of an undesirable effect*

II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 11 February 1992

concerning the summary notification information format referred to in Article 12 of Council Directive 90/220/EEC

(92/146/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (1), and in particular Article 12 thereof,

Whereas the competent authorities appointed by the Member States shall forward to the Commission dossiers for notifications received under Part C of Directive 90/220/EEC;

Whereas each dossier forwarded to the Commission shall include a summary of the notification;

Whereas the Commission is required to establish, before 23 October 1991, the format of this summary;

Whereas the provisions of this Decision have received the favourable opinion of the Committee of Member State Representatives in accordance with the procedure laid down in Article 21 of Directive 90/220/EEC,

HAS ADOPTED THIS DECISION:

Article 1

The competent authorities appointed by Member States under Directive 90/220/EEC must use the annexed Summary Notification Information Format when sending to the Commission the summary of a notification received, as specified under Part C of Directive 90/220/EEC.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 11 February 1992.

For the Commission

Carlo RIPA Di MEANA

Member of the Commission

(1) OJ No L 117, 8. 5. 1990, p. 15.

ANNEX

SUMMARY NOTIFICATION INFORMATION FORMAT FOR PRODUCTS CONTAINING GENETIALLY MODIFIED ORGANISMS (GMOS)

in accordance with Article 12 of Directive 90/220/EEC

INTRODUCTION

The present document is designed to serve as the format of the summary of the dossier submitted to the Commission for the placing on the market of a product containing GMOs (Part C, Article 12 (3) of Directive 90/220/EEC) and does not prejudice the provisions of Directive 90/220/EEC.

The summary notification information format for products containing GMOs when completed will contain a summary of the information entered under the corresponding points of the full dossier. It is, therefore, recognized that the risk assessment stipulated by Directive 90/220/EEC, Article 12, cannot be carried out on the basis of the summary.

A. *GENERAL INFORMATION*

1. *Details of notification*

(a) Member State of notification .....

(b) Notification number .....

(c) Name of the product (commercial and other names) .....

.....

(d) Date of acknowledgement of notification .....

.....

---

2. *Notifier / manufacturer / importer*

(a) Name of notifier .....

(b) Address of notifier .....

(c) The notifier is:

domestic manufacturer ☐

importer ☐

(d) In case of import

(i) Name of manufacturer .....

(ii) Address of manufacturer .....

---

3. *Characterisation of the GMOs contained in the product*

Indicate the name and nature of each type of GMO contained in the product

.....

.....

.....

.....

---

4. *General description of the product*

(a) Type of product

.....

.....

.....

(b) Composition of the product

.....

.....

.....

(c) Specificity of the product

.....

.....

.....

(d) Types of users

.....

.....

.....

(e) Exact conditions of use and handling

.....

.....

.....

(f) Geographical areas for which the product is intended

.....

.....

.....

(g) Type of environment for which the product is suited

.....

.....

.....

(h) Annual estimated production in and/or imports into the Community

.....

.....

.....

5. *Has the combination of GMOs contained in the product been notified under part B of Directive 90/220/EEC?*

Yes ☐ No ☐

(i) If *yes*, give country and notification number:

.....

.....

.....

(ii) If *no*, refer to risk analysis data on the basis of the elements of Part B of Directive 90/220/EEC.

.....

.....

.....

6. *Is the product being simultaneously notified to another Member State?*

Yes ☐ No ☐

If *yes*, please specify

.....

.....

.....

7. *Has another product with the same combination of GMOs been placed on the EC market by another notifier?*

Yes ☐ No ☐ Not known ☐

If yes, please specify

8. *Information on releases of the same GMOs or of the same combination of GMOs previously or currently notified and/or carried out by the notifier either inside or outside the Community*

9. *Specify instructions and or recommendations for storage and handling*

10. *Proposed packaging*

11. *Proposed labelling*

12. *Measures to take in case of unintended release or misuse*

13. *Measures for waste disposal and treatment*

B. *NATURE OF THE GMOS CONTAINED IN THE PRODUCT*

INFORMATION RELATING TO THE RECIPIENT OR PARENTAL ORGANISM(S) FROM WHICH THE GMO IS DERIVED

14. *Scientific name and other names*

15. *Phenotypic and genetic traits*

16. *Geographical distribution and natural habitat of the organisms*

17. *Genetic stability of the organism and factors affecting it*

18. *Potential for genetic transfer and exchange with other organisms*

19. *Information concerning reproduction and factors affecting it*

20. *Information on survival and factors affecting it*

21. *Ways of dissemination and factors affecting it*

22. *Interactions with the environment*

23 (a) *Detection techniques*

23 (b) *Identification techniques*

24. *Classification under existing Community rules concerning the protection of human health and/or the environment*

25 (a) *Pathogenic characteristics*

25 (b) *Other harmful characteristics of the organism living or dead, including its extracellular products*

26. *Nature and description of known extrachromosomal genetic elements*

27. *History of previous genetic modifications*

INFORMATION RELATING TO THE GENETIC MODIFICATION

28. *Methods used for the genetic modification*

29. *Characteristics of the vector*

(a) Nature and source of the vector

(b) Description of the vector construction

(c) Genetic map and/or restriction map of the vector

(d) Sequence data

(e) Information on the degree to which the vector contains sequences whose product or function area is not known

(f) Genetic transfer capabilities of the vector

(g) Frequency of mobilization of the vector

(h) Part of the vector which remains in the GMO

30. *Information on the insert*

(a) Methods used to construct the insert

(b) Restriction sites

(c) Sequence of the insert

(d) Origin and function of each constituent part of the insert in the GMO

(e) Information on the degree to which the insert is limited to the required function

(f) Location of the insert in the GMO

INFORMATION ON THE ORGANISM(S) FROM WHICH THE INSERT IS DERIVED (DONOR)

31. *Scientific and other names*

32 (a) *Pathogenic characteristics of the donor organism*

32 (b) *Other harmful characteristics of the organism living or dead, including its extracellular products*

33. *If the door organism has any pathogenic or harmful characteristics, indicate whether the donated sequences are in any way involved in them*

34. *Classification under existing Community rules relating to the protection of human health and the environment*

35. *Potential for natural exchange of genetic material between the donor(s) and recipient organism*

INFORMATION RELATING TO THE GMO(S) CONTAINED IN THE PRODUCT

36. *Description of genetic traits or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed*

37. *Genetic stability of the GMO*

38. *Rate and level of expression of the new genetic material*

39. *Activity of the expressed proteins*

40 (a) *Description of detection techniques for the GMO in the environment*

40 (b) *Description of identification techniques*

41. *Health considerations*

(a) toxic or allergenic effects of the non-viable GMOs and/or their metabolic products

(b) product hazards

(c) comparison of the GMO with the donor, recipient or parental organism regarding pathogenicity

(d) capacity for colonization

(e) If the organism is pathogenic to humans who are immuno-competent, supply the information specified in Annex II, Part II C 2 (i) (v)

INTERACTIONS OF THE GMO WITH THE ENVIRONMENT

42. *Survival, multiplication and dissemination of the GMO(s) in the environment*

43. *Interactions of the GMOs with the environment*

44. *Environmental impacts of the GMO(s)*

C. *PREDICTED BEHAVIOUR OF THE PRODUCT*

1. ENVIRONMENTAL IMPACT OF THE PRODUCT

2. HUMAN HEALTH EFFECTS OF THE PRODUCT

D. *INFORMATION RELATING TO PREVIOUS RELEASES*

I. HISTORY OF PREVIOUS RELEASES NOTIFIED UNDER PART B OF THE DIRECTIVE

1. *Notification number:* .....

2. *Release site:* .....

3. *Aim of the release:* .....

4. *Duration of the release:* .....

5. *Duration of post-release monitoring:* .....

6. *Aim of post-release monitoring:* .....

.....

7. *Conclusions of post-release monitoring:* .....

.....

.....

.....

8. *Results of the release in respect to any risk to human health and the environment (submitted to the competent authority according to Article 8 of Directive 90/220/EEC):*

.....

.....

.....

.....

II. HISTORY OF PREVIOUS RELEASES CARRIED OUT INSIDE OR OUTSIDE THE COMMUNITY

1. *Release country:* .....

2. *Authority overseeing the release:* .....

3. *Release site:* .....

4. *Aim of the release:* .....

5. *Duration of post-release monitoring:* .....

6. *Aim of post-release monitoring:* .....

.....

7. *Conclusions of post-release monitoring:* .....

.....

.....

.....

8. *Results of the release in respect to any risk to human health and the environment:*

.....

.....

.....

.....

III. HISTORY OF PREVIOUS WORK RELEVANT TO RISK ASSESSMENT PRIOR TO COMMERCIALIZATION

XI/619/91-Rev.3

GUIDANCE NOTES FOR THE NOTIFICATION FORMAT FOR PRODUCTS CONTAINING GMOs

(Article 12 of Directive 90/220/EEC)

INTRODUCTION

The present notes are intended to clarify and explain certain points of the Notification Format for products containing GMOs (Doc. XI/620/91-fin), thus providing guidance and facilitating its completion.

GENERAL INFORMATION (pages 4-9)

Paragraph 1

- Member State of notification: Please use the standard country codes.

Belgium	B	Italy	I
Denmark	DK	Luxembourg	L
France	F	Netherlands	NL
Ireland	IRL	Portugal	P
Germany	D	Spain	E
Greece	EL	United Kingdom	UK

- Notification number:

  It will be given by the Competent Authority and for products it should be preceded by C - for example C35.

Paragraph 2

c) If the notifier is neither a domestic manufacturer nor an importer, please indicate his function.

Paragraph 3

Name: For each type of GMO included in the product, need only include the name of the recipient or parental organism(s) with indications of the modified genetic function(s) and of the donor organism(s).

Nature: For each type of GMO included in the product, indicate what type of biological entity the GMO is: viroid, RNA virus, DNA virus, bacterium, fungus, plant, animal, etc.

Paragraph 4

a) Indicate whether the product is a vaccine, pesticide, crop plant, ornamental plant, bioremediation agent, diagnostic reagent, food or food ingredient, etc.

   Information on the physical form in which the product exists under the conditions of packaging and use (e.g. powder, aerosol, when appropriate, solution, solid crystalline, etc.), as well as information on the physiological form (e.g. seeds...), may be entered here.

b) In addition to the information entered under paragraph 3 (concerning the GMOs), give information on the additives or other components contained in the product.

c) Enter the particular properties of the product concerning its use (e.g. toxic action on a particular group of Dyptera).

d) Indicate whether the product will be used in industry, agriculture, skilled trades, contained facilities, State Agencies or by consumers, etc. If there are multiple users this should be stated.

e) Amongst other relevant information, here can be entered the frequency and method of application, dosage, measures to protect the user (if applicable), organisms on which the product is used, and restrictions of use (e.g. not to be used in winter, in drought, rainy season, etc.).

g) You may select from the list below for the general description of the environment for which the product is suited. A detailed description could be annexed.

1. Agricultural land, forestry and horticulture
2. Contaminated land
3. Mines
4. Industrial fermentors
5. Laboratories
6. Parts of buildings (e.g. cooling towers)
7. Animal farms
8. Fisheries (freshwater, coastal)
9. Marine environment
10. Recreation areas
11. Medical and veterinary practice
12. Food for general use
13. Others

Paragraph 5

i) Reference to part D, subpart A may be made

ii) Reference to part D, subpart C may be made

Paragraph 7

The question refers to other products (with different commercial names placed on the market by another notifier), which, though, contain the same combination of GMOs.

Paragraph 8

The following could be of relevance here:

- Information on whether the product was ever withdrawn from the market of a country outside the EEC for reasons of safety.

- Information on whether the product is already on the market of a country or countries outside the EEC.

- Information on whether the product has been rejected in a country outside the EEC for reasons of safety.

Paragraph 10

This must be appropriate so as to avoid unintended release of the GMOs during storage or at a later stage.

Paragraph 11

This must include, at least in summarised form, the information referred to in points A.1, A.2, A.3, B.1 and B.2 of Annex III A.

Paragraph 13

The question is applicable for some products only. Some examples: vaccines, biopesticides, and bioremediation agents.

B. NATURE OF THE GMOS CONTAINED IN THE PRODUCT

INFORMATION RELATING TO THE RECIPIENT OR PARENTAL ORGANISM(S)

Paragraphs 14-27 concern essential information on the biology of the recipient or parental organism(s) prior to genetic modification.

Recipient are the organisms which undergo a genetic modification (for instance, by introduction of a "foreign" gene transferred to them from a donor).

Parental are the organisms which largely contribute to the genome of the GMO. Parental organisms are those used in cell fusion experiments where the genome of the GMO is a hybrid of the genomes of the two parental organisms, neither of which can be consisted as recipient or donor.

Paragraph 14

Give sufficient information to accurately describe the organism: order or higher taxon (for animals), family (for plants), genus, species, subspecies, strain, serotype, cultivar, pathovar (biotype, ecotype, race, etc.) and common name. As much as possible, reference to taxonomic literature should be made.

Paragraph 15

Phenotypic or genetic markers that can be used to distinguish the organism, from natural close relatives may be entered here.

Other information which may be entered here, if relevant:

- Restriction and/or genetic map when the recipient or parental organism is a virus.
- Main restriction sites, relevant genetic and phenotypic traits for all other organisms.

Paragraph 16

The information on natural habitat could include mentioning of parasites, competitors, symbionts and hosts.

Paragraph 17

The extent and nature of any genetic instability in the organism and the conditions under which the stability of the organism is known to be affected may be entered here.

Paragraph 18

Describe whether the organism is able to transfer or exchange genetic information with other organisms, e.g. conjugation, cross-pollination, cross fertilisation or other forms of genetic transfer. In many instances, understanding will be incomplete, so summarise the present state of knowledge.

Paragraph 19

Describe how the organism is able to reproduce itself and if by more than one mode, indicate their relative importance. The relevant factors affecting the mode and rate of reproduction, could be indicated.

Paragraph 20

The survival forms of the organism, the time scale of survival (e.g. years for seeds or spores) and the relevant factors affecting it may be entered here.

Paragraph 21

Describe how the organism can spread in the environment and the relevant factors affecting dissemination.

Paragraph 22

For microorganisms, in particular, their involvement in main environmental processes such as primary production, nutrient turnover, decomposition of organic matter, respiration, etc., could be entered here.

Paragraph 23

The sensitivity, reliability and specificity of the detection and identification techniques should also be given here.

Paragraph 24

Relevant Community legislation is the following:

- Directive 90/679/EEC on the protection of workers from risks related to exposure to biological agents at work;
- Directive 77/93/EEC on the protective measures against the introduction into the Member States of organisms harmful to plants or plant products, as amended until now;
- Directive 64/432/EEC on animal health problems affecting intra-Community trade in bovine animals and swine;
- Directive 64/433/EEC on health problems affecting intra-Community trade in fresh meat;
- Directive 71/118/EEC on health problems affecting intra-Community trade in poultry meat;
- Directive 72/462/EEC on health and veterinary inspection problems upon importation of bovine animals and swine and fresh meat from third countries;
- Directive 82/894/EEC on the notification of animal diseases within the Community;
- Directive 90/426/EEC on animal health conditions governing the movement and import from third countries;
- Directive 91/67/EEC concerning the animal health conditions governing the placing on the market of aquaculture animals and products;
- Directive 91/68/EEC on animal health conditions governing intra-Community trade in ovine and caprine animals;
- Directive 91/69/EEC amending Directive 72/462/EEC on health and veterinary inspection problems upon importation of bovine animals and swine, fresh meat or meat products, in order to include ovine and caprine animals;
- Council Decision 90/424/EEC on expenditure in the veterinary field.

Paragraph 25

a) Describe whether the organism is pathogenic to any other organism and give information on infectivity, virulence, host-range, ability to colonise other organisms. Also, indicate whether the particular recipient or parental organism is a vector of a pathogen or can activate latent viruses, which is of importance, in case it has a wide host range with possibility to colonise other organisms.

b) The question refers to organisms, which living or dead, have harmful effects. Give information on toxigenicity and allergenicity (e.g. type of toxin produced and organisms affected).

Paragraph 26

The question related to the particular genotype which served as the recipient or parental organism and not to the species to which it belongs. The question does not concern mitochondrial or chloroplastic DNA. It can, however, concern viruses, viroids, transposons and indigenous plasmids.

Paragraph 27

The information is required only if the recipient or parental organism is already a GMO.

INFORMATION RELATING TO THE GENETIC MODIFICATION (paragraphs 28-30)

"Vectors" may be RNA or DNA sequences used for introducing the insert into the recipient organism.

"Insert" means all the sequences derived from the donor organism(s) and those of the vector which remain in the genome of the modified organism. In the case of plasmids or plasmid derived vectors, the insert comprises sequences from the donor organism(s) and those sequences of the vector which are useful or necessary for that particular genetic modification.

"Constituent part of the "insert" means any segment of DNA or RNA which either plays a role in DNA replication or gene expresion (e.g. regulatory genes, enhancers, promoters, etc.), or codes for structural proteins.

Paragraph 29

a) Give information on the nature of the vector (plasmid, bacteriophage, virus, cosmid, phagemid, transposable element, etc.) and its source.

b) Indicate the components of the vector and the organisms that contributed DNA sequences to it.

e) The relative position of these sequences should be shown on the restriction map.

g) The frequency of mobilization of the vector, when available, should be given together with the experimental conditions for measuring it.

h) The question concerns the cases when part of the vector remains in the GMO unintentionally.

Paragraph 30

d) For each constituent part of the insert, indicate its organism of origin.

e) If the insert is not limited to the required function, indicate the length of the extra sequences, their relative position to the other constituent parts and their possible function.

f) Relevant information, which may be entered here:

- number of copies inserted;
- number of insertion sites;
- number of functional copies inserted;
- location of the insert in the GMO. Information on whether the insert is located on a free plasmid or whether it is integrated in the chromosome. The exact position of the insert in the chromosome is not required here.

INFORMATION ON THE ORGANISM(S) FROM WHICH THE INSERT IS DERIVED
(paragraphs 31-35)

This section should be filled in for each of the donor organisms given in paragraph 30d.

Paragraphs 31, 34

The notes of the corresponding paragraphs 25, 24 apply here.

Paragraph 32

The notes of the corresponding paragraph 25 also apply here, provided the donated sequences are in some way linked to the pathogenic or harmful characteristics of the donor organism.

INFORMATION RELATING TO THE GMO(S) CONTAINED IN THE PRODUCT (paragraphs 36–44)

This section should be filled in for each type of GMO contained in the product, according to paragraph 3, page 4.

Paragraph 36

Describe how the introduced or deleted genetic material modifies the phenotype of the organism.

Paragraph 37

The question relates to the genetic stability of the insert in the GMO and the degree to which the introduced or deleted genetic material affected the stability of other genes in the organism. Particular attention should be paid to the extent to which the formulation and use of the product affects stability.

This should be examined in both the GMO obtained initially and the final GMO product after development through large scale culture fermentation stages or through all propagation phases of transgenic plants.

Paragraph 38

Give approximate expression levels of all genes inserted in the GMO, at mRNA and protein level.

If the inserted genes are expressed only in certain parts of the organism or during particular stages of its development, data on this specificity of expression should be provided.

Paragraph 39

The question concerns the biological activity of the proteins. For example, enzymatic, hormonal or physiological activity.

Paragraph 40

Describe how the GMO can be detected in the environment and how it can be identified. The sensitivity, reliability and specificity of the detection and identification techniques should also be given.

Paragraph 41

a) Toxic effects: This covers effects on all classes of organisms.
   Allergenic effects: this covers effects on all vertebrate animals (including humans).

b) The product hazards refer to effects on the biotic and abiotic natural environment.

c) Amongst others, a factor that could be taken into account here is the potential pathogenicity of the vector (if the vector remains in the GMO). The term pathogenicity here covers effects on all classes of organisms.

d) The question concerns the capacity of the GMO for colonisation of other organisms present in the environment, rather than its capacity for establishment in the environment.

INTERACTIONS OF THE GMO(S) WITH THE ENVIRONMENT

Paragraphs 42, 43, 44

Give a synthetic presentation of the respective results and/or conclusions obtained from the experimental releases or any other relevant testing work. Particular reference should be made to any data or results indicating differences between the GMO and the recipient or parental organisms. More specifically:

Paragraph 43

Amongst others, the information should also cover the following aspects: gene transfer, genetic stability in the environment, habitats where the GMO(s) could become established and significant interactions with other organisms in the environment.

Paragraph 44

Amongst others, the information should also cover the following aspects: selective advantage in the environment leading to excessive population growth and effects on non-target organisms.

PART C

Enter under this part the predicted environmental (A) and human health (B) impact of the product taking into account the overall composition of the product and its use.

PART D

Sub-part A has to be filled in for each experimental release, carried out under Part B of Directive 90/220/EEC, of the GMO(s) contained in the product.

Sub-part B has to be filled in for experimental or other releases of the GMOs contained in the product, which were carried out inside or outside the Community and were not covered by part B of Directive 90/220/EEC.

Sub-part C has to be filled in for any other work relevant for assessing the risk of the release of the product.

XI/635/91

STATEMENT OF THE COMPETENT AUTHORITY

concerning Notification _____
(notification number)

submitted according to Article 12.3 of Directive 90/220/EEC.

1. The present statement is transmitted to the Commission of the European Communities in accordance with Article 12 of Directive 90/220/EEC by the _____ Competent Authority in
(Member State)
connection with the notification numbered _____,
(notification number)
which concerns the placing on the market of _____.
(commercial name of product)

There are _____ annexes attached to this notification. They are numbered in accordance with the corresponding entry number in this dossier. The items which the notifier wishes to have considered as confidential and have been accepted as confidential by the Competent Authority are properly marked in this dossier.

2. According to Article 12.3 of Directive 90/220/EEC, the Competent Authority accepts the reasons given by the notifier for not supplying certain information specified in Annexes II and IIIB in accordance with the preamble to Annex II and Article 11.

3. The Competent Authority proposes to consent to the placing on the market of the product under the following conditions:

_____

_____

_____

Signature: _____

Name and position of the responsible official(s):

COMMISSION DECISION

of 21 May 1991

concerning a list of Community legislation referred to in Article 10 of Council Directive 90/220/EEC

(91/274/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (1), and in particular Article 10 thereof,

Whereas the Commission is required to establish, before the end of April 1991, a list of Community legislation which provides for a specific environmental risk assessment, similar to that laid down in Directive 90/220/EEC as regards products;

Whereas the Commission has examined the Community legislation in force and has not identified any such legislation;

Whereas this list will be re-examined periodically and, as necessary, revised;

Whereas the measures provided for in this Decision are in accordance with the opinion of the Committee of Member States representatives in accordance with the procedure laid down in Article 21 of Directive 90/220/EEC,

HAS ADOPTED THIS DECISION:

Article 1

At the date of this Decision, there is no Community legislation in force which provides for a specific environmental risk assessment of products which is similar to that laid down in Directive 90/220/EEC.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 21 May 1991.

For the Commission

Carlo RIPA DI MEANA

Member of the Commission

(1) OJ No L 117, 8. 5. 1990, p. 15.

XI/56/92-fin

PROCEDURE FOR CIRCULATION OF NOTIFICATIONS SUBMITTED UNDER DIRECTIVE 90/220/EEC

The procedures outlined below are designed to allow for the secure circulation of notifications or summaries which contain confidential information. While it is recognised there may be cases where there is no confidential information involved, the Commission intends to follow the same procedure to avoid confusion and recommends to Competent Authorities to do the same.

1. Procedure for Member States sending notifications (or notification summaries) to the Commission

1.1. The Competent Authorities send the notification to the Commission via the Permanent Representation of their country, for the attention of Mr. G. DEL BINO. The notification should be in an envelope within an envelope, and sealed with special labels, mentioning Directive 90/220/EEC (these will be shortly available from DG XI).

1.2 A fax should be addressed to the Commission (Mr. DEL BINO) from the C.A. indicating that the notifications have been sent (fax n°: 00-32-2-299.03.13).

1.3 When the notification contains confidential information, this should be clearly indicated. The confidential items/ paragraphs/documents should be easily identifiable, by means of a stamp, or a cover letter.

1.4 Notifications and/or notification summaries should be clearly numbered using the EC numbering system outlined under point 5.

1.5 Any additional information concerning a particular release should be sent to the Commission using the same procedure.

2. Procedure for circulation by the Commission:

2.1 On receiving the notification, the Commission indicates date of receipt on the document and numbers the pages received. It acknowledges receipt of the document by fax to the CA from whom the document has been received, indicating the date of circulation to other CAs.

2.2 Before circulation, the notifications are marked with the date of sending and are transmitted to the C.As in an envelope inside an envelope addressed to the Permanent Representation in Brussels, and marked for the attention of the appointed C.As. The envelopes are sealed with special, easily identifiable labels, mentioning the Directive. A numbered cover note inside the envelope identifies the items contained and helps keep track of the notifications circulated.

2.3 The Commission sends a telex/fax to the C.A. indicating that the notification has been sent to them on a particular date. The circulation will be carried out as soon as possible and will normally not exceed 3 working days.

3. Procedure for the C.A.s receiving notifications

3.1 Acknowledgment of receipt must be sent by fax/telex to the Commission, indicating date of receipt (for the attention of Mr. G. del Bino). It is important that this is sent.

3.2 Comments on the notification/notification summary should be sent either to the C.A. concerned with a copy to the Commission (Mr. G. del Bino), or to the Commission directly within 30 days from the date of circulation by the Commission. The Commission will forward immediately any comments received to the C.A. concerned, and will, as appropriate, eventually circulate the comments to other C.A.s for information.

If the comments concerning a notification contain confidential information, they must be sent by sealed letter via the Permanent Representations. For non-confidential notifications, the comments can be sent by ordinary mail or fax.

4. EC Numbering System for notifications

For part B notification, this is

B/(country code)/(year)/National Ref. No. (4 digit) and (optionally) a letter, if used in the national system

For part C, the scheme is the same, but B is replaced by C.

Examples: (Part B) B/NL/91/5 A (Netherlands)
Examples: (Part C) C/UK/92/1 (UK)

XI/621/91-fin

GUIDANCE ON INFORMATION NOT TO BE KEPT CONFIDENTIAL UNDER DIRECTIVE 90/220/EEC

A. Background

Directive 90/220/EEC on the Deliberate Release of GMOs to the environment foresee a system for identifying and protecting confidential information while at the same time it foresees that in the interest of transparency, a certain amount of basic information cannot be kept confidential. The Directive does not foresee whether information is made available actively or not. It should be noted that a considerable amount of information concerning specific GMOs and releases is publicly available in scientific literature, but especially in the patent applications which are often published prior to or at the same time as releases are made.

As regards confidentiality, Articles 19.1, 19.2 and 19.3 of the Directive establish a procedure whereby, following a dialogue between the notifier and the authorities, certain information can be agreed to be confidential, if there is a request from the notifier and if there is verifiable justification. It is implied that information cannot be automatically considered or accepted as confidential, and in practice in most cases it is expected that little information will be of a confidential nature.

Under Article 19.4, a number of items are listed as the information which the applicant and the authorities cannot keep confidential. These are:

- Description of the GMO or GMOs, name and address of the notifier, purpose of the release and location of release.

- Methods and plans for monitoring of the GMO or GMOs and for emergency response.

- The evaluation of foreseeable effects, in particular any pathogenic and/or ecologically disruptive effects.

As regards this minimum set of information which cannot be kept confidential, a number of experts have repeatedly expressed the wish to discuss further what is meant by Article 19.4 and a first exchange of views took place at the meeting of National Experts in October 1991. Even though it is up to the competent authorities to examine, on a case-by-case basis, confidentiality, it was felt that some guidance would be useful for interpreting Article 19.4, in order to avoid divergent national approaches.

This guidance is intended to assist in the understanding and implementation of the Directive. It is not intended to be an authoritative interpretation of the Directive; such interpretation can only be made by the European Council of Justice.

B. Guidance on interpretation

It should be emphasised that it is in the discretion of the authorities, in consultation with the applicant to discuss what is really confidential, as outlined under Article 19.1, 19.2 and 19.3 and what is not, with due respect to Article 19.4 of course. What must also be made clear is that once a competent authority has agreed with a notifier on what is to be kept confidential, no other authority has the right to disclose this information, as indicated under Article 19.1. If another Member State authority feels that the provisions of Article 19.4 have not been respected, then a complaint should be sent to the Commission for non-compliance with Article 19.4. In such cases, the Commission is obliged to investigate the matter, in dialogue with the competent authority responsible for the classification of information, and clarify whether Article 19.4 has been breached or not. In cases where, for whatever reason, the notification is withdrawn, confidentiality must be respected, as outlined in Article 19.5.

Taking each point under Article 19.4 in turn, the following more detailed guidance is suggested for discussion. As noted earlier in this paper, it should be kept in mind that a very large amount of information, often much more than outlined in Article 19.4, is often publicly available. Nevertheless, the information provided should not prejudice the possibility of patenting.

1. Description of the GMO or GMOs

This is the point for which it is perhaps most difficult to lay down generally applicable guidance, as there may be specific conditions applicable in certain cases. However, in principle, the following points are suggested as providing a description of the GMO(s) not to be considered confidential.

For deliberate release under Part C

Identity of each GMO contained in the product; introduced/modified traits and genes responsible for these traits; complete name of the recipient or of each parental organism; complete name of the organism from which the insert is derived; information relating to the genetic modification; function of each inserted DNA or RNA sequence or of deleted sequences; for modifications where base substitution occurs, description of the original function of the gene in which the base substitution occured and the function of the modified gene.

For deliberate release under Part B

Identity of GMO, including trait; complete name of the recipient or of each parental organism; information relating to the method of genetic modification; for modifications where base substitution occurs, description of the original function of the gene in which the base substitution occured and the function of the modified gene.

Whenever possible, information should also be kept non-confidential on: the name of organism from which insert is derived; and on the description of the function of each inserted DNA or RNA sequence or of deleted sequences.

2. Name and address of notifier

The name and official address of the research institute/company/manufacturer/importer, etc. is to be understood here. Names of individual persons can be kept confidential.

3. Purpose

(i) For a release under Part B. Reasons for which it is made, objectives of the release, parameters tested.

(ii) For a release through a product (Part C), the use the product is to be put to, and the type of users it is aimed at.

4. Location of the releases

Depending on the type of release, this could be the settlement where the site is (if a small plot in a town/village or attached to a specific installation), the bordering village(s) (if it is a field release in the middle of the countryside) or countries/regions (for the sale/testing of a product). An indication of the size of the release site or area and an indication of the expected spread of the organism may be relevant here. In some cases where the release is not taking place at a test site (e.g. vaccinated animals), the information not to be kept confidential should be such as to enable an estimate of the "wider site" (e.g. numbers of GMOs or GMO-infected individuals, the area within which they are expected to be found, etc., as well the area where, e.g. the bait has been laid, etc.).

5. Methods and plans for monitoring of the GMO

In principle, all the information submitted to the competent authorities.

6. Methods and plans for emergency response

In principle, all the information submitted to the competent authorities.

7. The evaluation of foreseeable effects, in particular any pathogenic and/or ecologically disruptive effects

The main idea behind this point is that the summary of the risk assessment carried out and the conclusions reached as regards foreseeable effects are not to be considered confidential. It is also important to have transparency concerning any conditions imposed on the release, in order to avoid any potential undesirable effects.

More specifically, as regards pathogenic effects, information not to be kept confidential should include the ability of the GMO and its extracellular products to be pathogenic or harmful in any other way to humans, plants or animals. The information submitted under Annex II, Section A 11.d and Section C 2.i. is particularly pertinent.

As regards possible ecologically disruptive effects, information not to be kept confidential should include information on the likelihood of post-release selection for the GMO, on the significant interactions with target and non-target organisms, on the ecosystems to which the GMO could be disseminated from the site of release and in which it could become established, on the likelihood of genetic exchange in vivo, and the relevant information on potential ecological impact (e.g. from simulated environments).

XI/140/91-fin

SCHEME FOR THE PROTECTION OF CONFIDENTIAL INFORMATION PROVIDED UNDER DIRECTIVE 90/220/EEC.

Introduction

Directive 90/220/EEC on the deliberate release of GMOs contain provisions for the protection of confidential information submitted by notifiers. A procedure is established for deciding which information items should be kept confidential, under Article 19.2, 19.3 and 19.4 of the Directive. Once it is clear that certain information is confidential, Article 19.1 places the Commission and the competent authorities under the legal obligation not to divulge to third parties any confidential information notified or otherwise provided under the Directive. It is important that adequate provisions are made to ensure the protection of confidential information.

The scheme of information protection proposed is based both on several years successful experience with handling confidential information for chemicals notified under Directive 79/831/EEC and on a Commission Decision SEC(86)1132 final, dated 7 July 1986, relating to classified documents and security measures applicable to such documents.

Draft Scheme

The different elements of the scheme are as follows:

1. Clear identification of confidential information

1.1 When confidential information is transmitted by a Member State authority to the Commission and hence to other Member States, the submitting authority must communicate this fact and identify the confidential items/paragraphs/documents clearly, either by means of an appropriate stamp next to the relevant items (e.g. "CONFIDENTIAL", "COMMERCIAL IN CONFIDENCE", etc.), or by an accompanying note giving confidentiality indications.

1.2 The Commission will ensure that confidentality protection requirements are clearly highlighted when transmitting this information to other Member States.

2. Secure storage of information

-Commission

2.1 Information received by the Commission (DG XI) will be kept in a safe with a combination lock in a Notification Room, which will be fitted with a special combination door lock and a special sound and flashing light alarm system. Any unauthorised entry sets off the alarm system which is directly connected to the Commission Security Office staffed on a 24-hr. basis.

2.2 As far as possible any work that needs to be done with confidential information will be carried out inside the notification room.

-Member States

2.3 Each competent authority in every Member State should make arrangements to have a safe or a security cabinet with a combination lock in a room that can be securely locked, so that information can be securely stored. Work using the confidential information should be done under Security conditions.

3 Strictly limited access to information

-Commission

3.1 Only a limited number of staff with specific authorisation given by an internal Commission procedure will be permitted to enter the Notification Room or handle confidential information. This authorisation is given after a special staff security clearance which involves national authorities, and after confidentiality protection undertakings have been signed.

3.2 If in future a computer is used to store or retrieve confidential data, it will be situated inside the notification room, and will only be handled by the authorised staff with special access codes.

3.3 Any copies of documents which are authorised for circulation to other Member States will be made on a photocopier inside the notification room, and will be strictly controlled, as far as possible.

3.4 If a translation or typing of documents containing confidential information received is necessary, it will be only done by the authorised staff mentioned above.

-Member States

3.5 Member State competent authorities must foresee a procedure for providing special authorization for anyone handling or having access to confidential information, and must keep a list of such authorised persons, who must have signed undertakings to protect confidentiality. Provisions for limiting access to confidential information similar to those outlined for the Commission under points 3.2-3.4 should be made.

4. Strictly controlled transmission of information

4.1 Notification documents containing confidential information transmitted between Member States and Commission must be placed inside double envelopes, sealed and marked with a special label.

4.2 Transport must be done by diplomatic bag between Member States capitals and the Member States Permanent Representations in Brussels, and by hand between the Commission and the Permanent Representations. To ensure that the packages arrive safely, at the moment of dispatch, the sender (Member State authority or the Commission, as appropriate) should send a telex announcing the dispatch and the content and, on receipt, the M.S. authorities or the Commission, as appropriate, must send a telex acknowledging safe arrival.

5. Strictly controlled circulation of confidential information

5.1 Circulation of confidential information must be extremely limited and on a need-to-know basis.

5.2 Member State authorities must undertake to provide as high a level of protection to information received from other Member States as they do to information received from their own notifiers, and thus limit circulation and access in the same way. This is pertinent both as regards the staff who have access to the information and as regards any member of an advisory committee.

5.3 No confidential information should be seen by anyone who has any potential commercial or other personal interest in that information. This potential interest must be determined by the Competent Authorities.

6. Control of Member State security procedures and facilities

6.1 Before any confidential information is sent for the first time to a Member State competent authority, the Commission will check that adequate provisions and procedures, are in operation in that particular Member State authority, by on-the-spot inspection if necessary. Member States must indicate to the Commission the state of readiness as soon as possible.

6.2 If a competent authority is considered not to be adequately equipped to handle confidential information, the envelopes with the relevant documents will not be sent to it. The information will be kept on behalf of the Member State in the safe of the Notification Room in Brussels, until such time as the Member State authority is ready and equipped to receive it.

6.3 Every Member State authority must sign a letter addressed to the Commission, undertaking to protect confidential information, verifying that the necessary measures have been taken, and indicating the names of the persons authorized to see confidential information.

6.4 The Commission will keep an updated list of all the those authorised to handle confidential information in all the Member States.

XI/57/92-fin

GUIDANCE FOR INTERPRETATION OF THE TERM "PLACING ON THE MARKET" WITH REFERENCE TO DIRECTIVE 90/220/EEC

One of the objectives of Directive 90/220/EEC is to establish the mechanisms for ensuring that human health and the environment are protected when products are placed on the market containing or consisting of genetically modified organisms.

A "product" is defined as "a preparation consisting of, or containing, a GMO or combination of GMOs, which is placed on the market" (Article 2.4) and "placing on the market" is defined as "supplying or making available to third parties" (Article 2.5). The procedures for assessing these products and giving consent is established under Part C of the Directive "Placing on the market of products containing GMOs" (Articles 10-18).

Some confusion has arisen from the use of the definition "supplying or making available to third parties". Apart from products freely available on the commercial market ("on the shelf" or in catalogues, for example), which are clearly products to be approved for placing on the market, there has been some ambiguity as to whether this covers a range of other exchanges such as:- non-commercial exchanges between two or several research institutions, bilateral semi-commercial or commercial exchanges between companies and research institutions or between parent companies and subsidiaries, depositing microorganisms at recognised depositary authorities for the purposes of patent procedure, supplying microorganisms from culture collections.

It has therefore become necessary for some guidance to be provided on the interpretation of the term "placing on the market" in the context of the Directive. This guidance is intended to assist in the understanding and implementation of the Directive. It is not intended to be an authoritative interpretation of the Directive; such interpretation can only be made by the European Court of Justice.

The statement made by the Commission and the Member States at the time of adoption of the Directive gives some first guidance on this issue. This stated that "material specifically developed for a user on a bilateral agreement between a supplier and a user and which will be used for research and development purposes will not be considered as requiring consent for placing on the market provided its use in research is subsequently notified under Part B of the Directive". This therefore indicates that if a GMO is developed by one organisation (research institute or company) but supplied in order to be tested under Part B by another, it is not considered as "placing on the market", even though it is "supplied" or "made available".

A further question arises as to GMOs exchanged for non-commercial purposes between two research institutions, but which will be used only for "contained use" experimental work (as defined in Directive 90/219/EEC) and will not be notified under Part B of Directive 90/220/EEC. In the letter of Directive 90/220/EEC this could be interpreted to fall under the term "Supplying or making available to third parties". However, the spirit of the Directive is to ensure that no GMOs are used without adequate safeguards. It is important that the Contained Use and the Deliberate Release Directives are seen as complementary and that they are both taken into account in interpreting the measures necessary for the protection of human health and the environment. If the research institutions in such an exchange have been duly notified and registered as suitable for undertaking work with GMMs under Directive 90/219/EEC, then the non-commercial exchange of a GMM (falling within the Group for which the receiving institution has been notified) could be considered as not being required to fulfil the condition of placing on the market.

A similar question arises as to exchanges within subsidiaries of the same company or the research company and the production company within the same group of companies. There again, if the exchange is by bilateral agreement, and does not concern a GMM to be made more widely available to others as a product, and provided that the receiving company/section of the company has been duly notified under Directive 90/219/EEC as an installation suitable for GMO work with that Group of GMOs, such an exchange could be considered as not being required to fulfil the condition of placing on the market.

Similarly, if a GMM is deposited at a recognised depositary authority for the purposes of patent procedure, as foreseen under the Budapest Convention, provided that the culture bank where it is deposited and stored is duly notified under Directive 90/219/EEC, the deposition could be considered as not being required to fulfil the conditions for placing on the market.

It should be noted that the question of adequate provisions for the transport between two institutions undertaking contained use operations is important and that the gaps existing in that area need to be covered. There is a significant gap when the GMOs exchanged have not been cleared for placing on the market.

The interpretation of what constitutes a "product" also appears to cause some confusion. According to the definition in the Directive, products are GMOs placed on the market (Article 2.4), but Article 1, refers to the placing on the market of GMO products "intended for subsequent deliberate release into the environment". The "deliberate release" is defined as "any intentional introduction of GMOs without provisions for containment ....to limit their contact with the general population and the environment". A statement made in the Council by the Commission and the Member States, however, further defines "intentional introduction" as "the introduction by whatever means, directly or indirectly, by using, storing, disposing, or making available to a third party, of a GMO or a combination of GMOs". Some terms, such as "storing" are not defined. A definition of "use" is given in the Directive as "the deliberate release of a product which has been placed on the market".

The question that has arisen is whether a commercially available GMO, on its own or as part of a preparation or a kit, widely available (e.g. through a catalogue), should be considered as a "product" in the sense of Directive 90/220/EEC, even though the use foreseen is not wide dissemination in a field or in the open environment but use inside a laboratory, hospital or indeed possibly a private home or other establishment.

The first point to note is that Article 11 places an obligation on a manufacturer or importer to notify the Competent Authorities before placing on the market a product for the first time, without any mention of the purpose of the product being made in this article.

Secondly, the spirit as well as the letter of both Directives has to be examined. Taking all the provisions of both Directives together, the significant element is that anyone using a GMO must either do so in contained use conditions following the notification procedures of Directive 90/219/EEC, or under the specific consent conditions of Part B of 90/220/EEC, or otherwise, can purchase and use a GMO-containing product freely, as a user, if the product has received the consent under Part C of Directive 90/220/EEC.

It is clear in the Directive that if a GMO-containing product, whatever its purpose, has not received consent under Part C, it cannot be used by anyone without prior notification. It is evident that, unless the exchange is the result of specific agreement between two parties (as discussed earlier in this text), there is no possibility either for the authorities or the person placing on the market to control the purchaser and whether the installation using the product is notified (e.g. when a product is offered in a catalogue).

A logical conclusion would therefore be that it is both in the spirit and the letter of the Directives that the act of placing a GMO or GMO-containing product freely on the market constitutes a release and therefore needs to fulfil the provisions of Part C or Directive 90/220/EEC.

Conclusions

Despite the wide definition of "placing on the market" in Directive 90/220/EEC, which defines it as "supplying or making available to third parties" (Art. 2.5), there are carefully considered cases in certain circumstances, where a GMO containing product within the scope of 90/220/EEC which is supplied or made available to a third party could nonetheless be considered as not requiring approval under Part C of Directive 90/220/EEC.

The following are such cases:

(i) Material specifically developed for a user on a bilateral agreement between a supplier and a user, provided its use is intended to be notified under Part B of Directive 90/220/EEC.

(ii) GMMs exchanged for non-commercial purposes between two research institutions but which will be used only for "contained use" (as defined in Directive 90/219/EEC), provided that both the research institutions in such an exchange have been duly notified and registered under Directive 90/219/EEC as suitable for undertaking work with GMMs, and provided that the non-commercial exchange of the GMM falls within the group for which the receiving institute has been notified.

iii) Exchange of a GMM within subsidiaries of the same company or the research company and the production company within the same group of companies, where the exchange is by bilateral agreement, does not concern a GMM to be made more widely available to others as a product, and provided that the receiving company/section of a company has been duly notified under Directive 90/219/EEC as an installation suitable for GMM work with that group of GMMs.

iv) Deposition of a GMM at a depository authority, including deposition for the purposes of patent procedure, provided that the culture bank where the GMM is stored is duly notified under Directive 90/219/EEC.

v) The supply of GMMs (for which an administrative charge may be made), from culture collections, which are notified installations under Directive 90/219/EEC, to other centres which have also been duly notified under Directive 90/219/EEC as installations suitable for GMM work with that group of GMMs.

XI/88/91-fin

RULES OF PROCEDURE FOR THE COMMITTEE ON

THE RELEASE OF GMOs TO THE ENVIRONMENT

The Committee on the release of genetically modified organisms to the environment,

HAVING REGARD to the Council Directive 90/220/EEC[1] of 23 April 1990 on the deliberate release of genetically modified organisms to the environment and, in particular, Article 21 thereof.

HAS LAID DOWN ITS RULES OF PROCEDURE AS FOLLOWS:

Article 1

1.1 The Committee shall be convened by its Chairman, either on his own initiative or at the request of the representative of a Member State.

Article 2

2.1 The Chairman shall draw up the agenda and any question, the discussion of which has been requested in writing by the representative of a Member State, must be dealt with in a Committee meeting as soon as possible and within a maximum of three months of receipt.

2.2 In the case where the Commission must carry out extensive preparatory work on the draft provisions which are submitted to the Committee, the maximum time limit is six months.

Article 3

3.1 Letters convening meetings, the agenda, draft provisions and any other working documents shall be sent by the Chairman to the Member States' representatives on the Committee in accordance with the procedure provided for under Article 11, Para. 2. These documents must reach the Permanent Representations of the Member States not later than 28 days before the meeting is due to take place, in all the Community languages.

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(1) O.J. N° L117 of 8.05.1990

3.2 In urgent cases, at the request of the representative of a Member State or on his own initiative, the Chairman may reduce this period to no less than 14 days, stating his reasons thereof.

3.3 In case of non respect of these limits, the meeting shall be postponed by the Chairman to a later date if the representative of a Member State requests it.

Article 4

4.1 The Committee delivers its opinion on the measures proposed by the Commission, according to the procedures laid down in Article 21 of Directive 90/220/EEC.

4.2 In the event that an Opinion is requested on a text to which an amendment is made during the discussion, the Chairman:

- may defer the vote to the end of the meeting or to the following meeting, whose date must then be fixed;
- must postpone the vote until the following meeting, whose date must then be fixed, if requested to do so by the representative of a Member State.

Article 5

5.1 Where the Committee has not issued an Opinion within the time limit set by the Chairman, the latter may postpone the vote until the following meeting.

Article 6

6.1 Each Member State shall appoint its representative to the Committee. The Commission will only cover the expenses for two representatives per Member State. A Member State can represent one other Member State. The Chairman shall be informed thereof by the Permanent Representation of the Member State thus represented.

6.2 The quorum required for the deliberations of the Committee to be valid shall be that required to render an opinion according to the procedures laid down in Article 21 of Directive 90/220/EEC.

Article 7

7.1 The Secretariat to the Committee shall be provided by the Commission's services.

Article 8

8.1 Before any opinion is requested from the Committee, any amendments proposed to the drafts previously circulated as mentioned under Article 3 shall be submitted to it in writing.

8.2 A list of the decisions made shall be presented to the Committee before the end of the meeting for approval. In addition, a summary of the conclusions of each meeting shall be prepared and submitted to the Committee for approval at a subsequent meeting.

Article 9

9.1 The Committee may set up sub-Committees, chaired by the Commission, to prepare its work or carry out specific tasks. The Members of these sub-Committees must be appointed by the Member States. Sub-Committees will only play an advisory role and will not have power to vote.

Article 10

10.1 The Committee may grant a hearing to non-governmental experts if there is no opposition on the part of any representative of a Member State. These experts shall take no part in either the deliberations or the voting of the Committee.

Article 11

11.1 All correspondence concerning the Committee shall be addressed to the Commission, in particular to the Directorate-General for the Environment, Nuclear Safety and Civil Protection, for unless the Member States are otherwise advised by the Commission.

11.2 Any correspondence for the representative of the Member States and the Committee shall be addressed to the Permanent Representations; copies of documents shall be sent directly and simultaneously to a limited number of officials appointed by these Member States, provided the Member States have notified the Commission of the names and addresses of these officials.

Article 12

12.1 In conformity with Article 214 of the Treaty, and without prejudice to Article 19 of Directive 90/220/EEC, the deliberations of the Committee shall be of a confidential nature.

Adopted in Brussels on 25 March 1991

COMMISSION DECISION

of 22 October 1993

establishing the criteria for simplified procedures concerning the deliberate release into the environment of genetically modified plants pursuant to Article 6 (5) of Council Directive 90/220/EEC

(93/584/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (1), and in particular Article 6 (5) thereof,

Whereas, where a competent authority considers that sufficient experience has been obtained of releases of certain genetically modified organisms (GMOs), it may submit to the Commission a request for the application of simplified procedures for the release for such types of GMOs, and whereas the Commission is required to establish criteria based on safety to human health and the environment and on the exidence available on such safety, to enable the Commission to decide whether a specific simplified procedure should be approved;

Whereas there is now accumulated knowledge and data available concerning the necessary prerequisites for safety to human health and the environment for the release of certain types of GMOs;

Whereas it is considered appropriate that given the different safety concerns for different types of organsims, separate criteria should be established for plants, animals and micro-organisms and that accordingly, the criteria established by this Decision are applicable only in relation to genetically modified plants, which is the group of GMOs with which most of the experience has been acquired to date;

Whereas evidence from releases of genetically modified plants has indicated that the safety of releases of such plants depends on the characteristics of the recipient plant species, on the characteristics of the inserted sequences and their products, and on the receiving ecosystems, and whereas the criteria to be established should be aimed specifically at the evaluation of these characteristics;

Whereas these criteria form an objective and harmonized basis for decisions on the requests for application of simplified procedures;

Whereas is is appropriate, in the interest of transparency, to establish a uniform procedure for the making of a request for simplified procedures;

Whereas, such a request should be based on experience with the GMOs under consideration and on the evidence of safety for human health and the environment and whereas, to these ends, it is appropriate that this experience may include the competent authority's own experience with releases of the same GMOs and the experience in similar ecosystems whether within the Community or internationally, of the GMOs under consideration;

Whereas it is important, in the interests of the greatest possible applicability of uniform procedures, compatible with considerations of safety to human health and the environment, that all Member States should have the opportunity to join in any request for the application of simplified procedures and whereas to this effect an appropriate procedure should be established;

Whereas this Decision is in accordance with the opinion of the Committee established under Article 21 of Directive 90/220/EEC,

HAS ADOPTED THIS DECISION:

Article 1

1. The Commission shall take a decision on the application for simplified procedures for the deliberate release of genetically modified plants, as required under Article 6 (5) of Directive 90/220/EEC, by reference to the criteria set out in paragraphs 2, 3 and 4 and by reference to the sufficient experience and evidence thereof referred to in Article 2.

2. The criteria relating to the characteristics of the recipient plant species shall be as follows:

(a) the taxonomic status and the biology (mode of reproduction and pollination, ability to cross with related species), should be well-known,

(1) OJ No L 117, 8. 5. 1990, p. 15.

and

information should be available on any interactions of particular relevance for the evaluation of risk, involving the recipient plant species and other organisms in agricultural ecosystems or in the experimental release ecosystem,

and

(c) scientific data should be available on the safety for human health and the environment of experimental releases involving genetically modified plants of the same recipient plant species.

The criteria relating to the characteristics of the erted sequences and their expression products shall be follows:

the inserted sequences and their expression products should be safe for human health and the environment under the conditions of the experimental release,

and

the inserted sequences should be:

— well characterized, and

— integrated into the plant nuclear genome.

The criterion relating to the characteristics of the field release experiments shall be that whenever necessary, : appropriate practices for the management of risks will applied during or after the experimental release, to sure the protection of human health and the environment.

The criteria set out in paragraphs 2 and 3 should be plied in every case whereas the criterion set out in paragraph 4 should be taken into account when examining a)posed simplified procedure and applied as appropriate.

Article 2

A request for the application of simplified proceres shall be made in accordance with the procedures laid down in paragraphs 2 and 3 and Article 3:

2. The request shall be submitted to the Commission in writing and shall be accompanied by a dossier which shall include a description of the proposed simplified procedures, the conditions (if any) under which they are to be applied and information and data on the sufficient experience which has been obtained of releases of the GMOs under consideration.

3. Sufficient experience shall show that the GMOs under consideration are safe for human health and the environment and may be based on the competent authority's own experience with release of the same GMOs, experience with releases of the GMOs under consideration in similar ecosystems and international experience.

Article 3

1. On receipt of the request and the accompanying dossier, the Commission shall immediately forward to the competent authorities of the other Member States a copy of the said request and accompanying dossier.

2. Within 45 days following the dispatch of the request and accompanying dossier, any other competent authority may notify the Commission in writing of its intention to join in the request. To that end, the competent authority may submit any further or additional evidence in support of the original request.

3. Upon expiry of the time limit specified in paragraph 2, the Commission shall forthwith take a decision on the request in accordance with the procedure laid down in Article 21 of Directive 90/220/EEC.

Article 4

This Decision is addressed to the Member States.

Done at Brussels, 22 October 1993.

For the Commission

Yannis PALEOKRASSAS

Member of the Commission

II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 4 November 1994

establishing simplified procedures concerning the deliberate release into the environment of genetically modified plants pursuant to Article 6 (5) of Council Directive 90/220/EEC

(Only the Danish, Dutch, English, French, German, Italian, Portuguese and Spanish texts are authentic)

(94/730/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (1), as last amended by Commission Directive 94/15/EC (2), and in particular Article 6 (5) thereof,

Whereas, where a competent authority considers that sufficient experience has been obtained of releases of certain genetically modified organisms (GMOs), it may submit to the Commission a request for the application of simplified procedures for the release for such types of GMOs;

Whereas such a request has been submitted by the competent authorities of the Member States who consider that sufficient experience has been obtained of releases of certain genetically modified plants;

Whereas Commission Decision 93/584/EEC (3) establishes the criteria to enable the Commission to decide on the application of simplified procedures; whereas these criteria are based on safety to human health and the environment and on the evidence available on such safety;

Whereas the Commission has examined the requests submitted by the United Kingdom and France for the application of simplified procedures for certain releases of genetically modified plants and the evidence submitted, and has subsequently evaluated these requests in the light of the criteria already established;

Whereas the Commission has concluded that the requested simplified procedures are in conformity with the established criteria, and that sufficient experience has been obtained of releases of certain GMOs to justify the introduction of the requested simplified procedures;

Whereas it is important, in the interests of the greatest possible applicability of uniform procedures, compatible with considerations of safety to human health and the environment, that all Member States should have the opportunity to join in any request for the application of simplified procedures; whereas to this effect an appropriate procedure has been established;

Whereas in accordance with that procedure the competent authorities of France, the United Kingdom, Belgium, Italy, Portugal, Ireland, Spain, Denmark, the Netherlands and the Federal Republic of Germany have notified the Commission of their intention to apply the simplified procedures foreseen in this Decision;

Whereas this Decision is in accordance with the opinion of the Committee established pursuant to Article 21 of Directive 90/220/EEC,

(1) OJ No L 117, 8. 5. 1990, p. 15.
(2) OJ No L 103, 22. 4. 1994, p. 20.
(3) OJ No L 279, 12. 11. 1993, p. 42.

HAS ADOPTED THIS DECISION:

Article 1

The requests submitted by France and the United Kingdom pursuant to Article 6(5) of Directive 90/220/EEC and concerning the simplified procedures set out in the Annex are approved.

Article 2

This Decision is addressed to the Kingdom of Belgium, the Kingdom of Denmark, the Federal Republic of Germany, the Kingdom of Spain, the French Republic, Ireland, the Italian Republic, the Kingdom of the Netherlands, the Portuguese Republic and the United Kingdom of Great Britain and Northern Ireland.

Done at Brussels, 4 November 1994.

For the Commission

Yannis PALEOKRASSAS

Member of the Commission

ANNEX

1. The simplified procedure provides for a single notification dossier to be submitted pursuant to Part B of Directive 90/220/EEC, for more than one release of genetically modified plants which have resulted from the same recipient crop plant species but which may differ in any of the inserted/deleted sequences or have the same inserted/deleted sequence but differ in phenotypes.

2. A notifier can submit in a single notification information on several releases of genetically modified crop plants, to be released on several different sites, on the following conditions:

   — the taxononic status and biology of the recipient plants species is well known,

   — information is available on the interactions of the recipient plant species in the ecosystems in which the experimental and/or agricultural releases are scheduled,

   — scientific data is available on the safety to human health and the environment of experimental releases involving genetically modified plants of the same recipient plant species,

   — the inserted sequences and their expression products should be safe for human health and the environment under the conditions of the experimental release,

   — the inserted sequences have been well characterized,

   — all the inserted sequences are integrated into the plant nuclear genome,

   — all the releases are for an a priori specified programme of work,

   — all the releases take place within an a priori specified time period.

3. The information required in the notification is that indicated in Annex II to Directive 90/220/EEC.

4. Only one single consent is required for all the releases described in the single notification submitted to the competent authority. The procedure to be used in granting that consent is that outlined in Part B of Directive 90/220/EEC.

5. In order to obtain one single consent covering several releases, all the necessary information for each release should be indicated in the single notification, including sufficient information on the different sites of the releases and on the experimental design, as well as indication of any conditions for risk management for each different release. Clear reference to each release to be covered should be made in the notification, and the appropriate information should be included to allow completion of the summary notification information format.

6. A notifier can also submit a single notification covering a whole, a priori specified, programme of development work with a single specific recipient plant species and a specified range of inserts/deletions over several years and on several different sites, and receive a single consent for the whole programme of work.

6.1. In such cases, detailed indications or descriptions of the different sites of the releases, subsequent intraspecific sexual crosses and/or the conditions of release need not be given in the notification, as would be required under the conditions indicated in paragraph 5. However, the notification must contain sufficient information to enable overall an evaluation of risk, and a detailed risk assessment to be made for at least the first release in the programme of work. The information that need not be given may only relate to the sites of the releases, the description of the sites and their surface area, the number of plants released, and the subsequent sexual crosses of the initially notified plants (including progenies) with themselves and/or with plant lines of the initially notified recipient plant species (including the progenies of these crossings).

7. In the cases referred to in paragraph 6.1 the notifier will submit to the competent authority the additional information together with a statement indicating whether the original risk assessment remains valid and if not, provide further evaluation. This information should be sent before the specific release to which it refers is carried out, in the form of a simple additional notice for information only.

7.1. The competent authority will immediately send to the Commission any additional risk assessment associated information received in application of paragraph 7. The Commission will circulate these to the competent authorities of the other Member States for information only.

7.2. The notifier can proceed with the release in question after 15 days from the date of receipt by the competent authority of this additional information, unless he receives written indication from the competent authority.

7.3. If any new information submitted is such that the original consent under simplified procedures is no longer applicable, then it is for the competent authority to indicate to the notifier within 15 days of receipt of the notification that he may only proceed with the intended release if a consent is granted under the standard procedure laid down in the Directive.

8. When the single consent under simplified procedures is granted, conditions can be attached to each of the releases to which it refers. These conditions can subsequently be altered by the competent authority, as indicated in Article 6(6) of the Directive.

9. On completion of one or more of the releases approved within the simplified procedure, the notifier shall submit to the competent authority a report with the results of the release(s) at the time specified in the consent. Such reports may be submitted separately, or as a clearly identifiable section in support of a notification for subsequent releases.

10. The competent authority may alter the conditions of the original consent or intervene to alter the conditions of specific subsequent releases on the basis of the results indicated in the reports or on the basis of information obtained during inspections.

ANNEX

1. The simplified procedure provides for a single notification dossier to be submitted pursuant to Part B of Directive 90/220/EEC, for more than one release of genetically modified plants which have resulted from the same recipient crop plant species but which may differ in any of the inserted/deleted sequences or have the same inserted/deleted sequence but differ in phenotypes.

2. A notifier can submit in a single notification information on several releases of genetically modified crop plants, to be released on several different sites, on the following conditions:

   — the taxononic status and biology of the recipient plants species is well known,

   — information is available on the interactions of the recipient plant species in the ecosystems in which the experimental and/or agricultural releases are scheduled,

   — scientific data is available on the safety to human health and the environment of experimental releases involving genetically modified plants of the same recipient plant species,

   — the inserted sequences and their expression products should be safe for human health and the environment under the conditions of the experimental release,

   — the inserted sequences have been well characterized,

   — all the inserted sequences are integrated into the plant nuclear genome,

   — all the releases are for an a priori specified programme of work,

   — all the releases take place within an a priori specified time period.

3. The information required in the notification is that indicated in Annex II to Directive 90/220/EEC.

4. Only one single consent is required for all the releases described in the single notification submitted to the competent authority. The procedure to be used in granting that consent is that outlined in Part B of Directive 90/220/EEC.

5. In order to obtain one single consent covering several releases, all the necessary information for each release should be indicated in the single notification, including sufficient information on the different sites of the releases and on the experimental design, as well as indication of any conditions for risk management for each different release. Clear reference to each release to be covered should be made in the notification, and the appropriate information should be included to allow completion of the summary notification information format.

6. A notifier can also submit a single notification covering a whole, a priori specified, programme of development work with a single specific recipient plant species and a specified range of inserts/deletions over several years and on several different sites, and receive a single consent for the whole programme of work.

6.1. In such cases, detailed indications or descriptions of the different sites of the releases, subsequent intraspecific sexual crosses and/or the conditions of release need not be given in the notification, as would be required under the conditions indicated in paragraph 5. However, the notification must contain sufficient information to enable overall an evaluation of risk, and a detailed risk assessment to be made for at least the first release in the programme of work. The information that need not be given may only relate to the sites of the releases, the description of the sites and their surface area, the number of plants released, and the subsequent sexual crosses of the initially notified plants (including progenies) with themselves and/or with plant lines of the initially notified recipient plant species (including the progenies of these crossings).

7. In the cases referred to in paragraph 6.1 the notifier will submit to the competent authority the additional information together with a statement indicating whether the original risk assessment remains valid and if not, provide further evaluation. This information should be sent before the specific release to which it refers is carried out, in the form of a simple additional notice for information only.

7.1. The competent authority will immediately send to the Commission any additional risk assessment associated information received in application of paragraph 7. The Commission will circulate these to the competent authorities of the other Member States for information only.